

EN - Declaration of Conformity

We, the manufacturer,

Key Surgical LLC
 8101 Wallace Rd.
 Eden Prairie, MN 55344
 USA

ensure and declare with sole responsibility, that the following Class I non-sterile (per MDR), non- reusable, non-measuring medical devices meet the provisions of the EU Medical Device Regulation 2017/745 (MDR) Annex IV for Medical Devices, which apply to them. These devices are in conformity to the Medical Device Regulation 2017/745 that provides for the issuing of the EU declaration of conformity. All supporting documentation is retained under the premises of the manufacturer.

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
Cleaning Brushes	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	084977100000000000000001M3	There are no common specifications set forth by the European Commission under MDR that apply to Key Surgical product in this Declaration. Applied recognized standards are identified in technical documentation.
	Intended Purpose: Cleaning of medical devices	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336 09338	UMDNS: 21-134 GMDN: 34878 & 38835		

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	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197		

		BR-31-276 BR-3201 BR-3201-50 BR-4140		
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600		
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325		
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50		

BR-075-24
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	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21-134 GMDN: 38835	
Irrigation Cannulas Intended Purpose: Intended for use in wound irrigation.	Key Surgical Cannulas (non-sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15-206 GMDN: 62389	0849771000000000000002M5
Instrument Protectors Intended Purpose: Intended to cover and protect medical instruments.	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06-01, 01800, 3-06-02, I3-06-02, 01801, 3-06-03, I3-06-03, 01802, 3-06-04, I3-06-04, 01803, 3-06-05, I3-06-05, 01804, 3-06-07, I3-06-07, 01805, 3-11-01, I3-11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11-03, 01828, 3-11-04, I3-11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12-01, 01838, 3-12-02, I3-12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, I3-12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12-09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10-04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09-03, 01814, 3-09-04, I3-09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09-08, I3-09-08, 01472,	UMDNS: 16-222 GMDN: 63247	0849771000000000000003M7

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	<p>Key Surgical Instrument Tip Protectors</p>	<p>PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004</p>			

K-Wire and Pin Covers Intended Purpose: Protect and cover K-wires and pins.		H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457		
	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS		
Instrument Sterilization Tray Intended Purpose: Protection of devices in cleaning, sterilization and storage.	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDMS:12-143 GMDN:13730	0849771000000000000004M9
	Key Surgical Finger Mat	FM-1810		
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50		

		DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Tray Corner Protectors Intended Purpose: Protect sterilization tray corners and sterilization wrap	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15- 907 GMDN: 63494 & 65133	08497710000000000000005MB	
Adhesive Remover Intended Purpose: Solution for removing adhesive residue from medical instruments	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN:64150	08497710000000000000006MD	
Hot Air Film Intended Purpose: Intended for use in Hot Air Sterilization methods	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735	08497710000000000000007MF	
Sterilization Wrap Intended Purpose: Sterile Barrier Wrap	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075	UMDNS: GMDN: 13735	08497710000000000000008MH	

CB/TWO090
CB/TWO100
CB/TWO120
CB/TWR120
CB/TWRAP060
CB/TWRAP075
CB/TWRAP090
CB/TWRAP100
CB/TWRAP1012
CB/TWRAP120
CB/TWRAP1315
CB/TWRAP1315X
CB/TWRAP150
CB/TWRAP150F3W
CB/TWRAP18135
CB/TWRAP1815
CB/TWRAP5075
CB/TWRAPDRY050
CB/TWRAPDRY060
CB/TWRAPDRY075
CB/TWRAPDRY090
CB/TWRAPDRY100
CB/TWRAPDRY120
CB/TWRAPDRY1315X
CB/TWRAPDRY140
CB/TWY100
CB/TWY120
CB030
CB050
CB060
CB075
CB090
CB100
CB100DB
CB1012
CB1014
CB120
CB120DB
CB1315
CB1315DB
CB140
CB150
CB1540
CB1715
CB1715DB
CB1815
CB1815DB
CBA/TWRAP120
CBA/TWRAP140
CBA050
CBA075
CBA090
CBA100
CBA120
CBA1415
CBU/TWRAP100
CBU/TWRAP1215
CBU/TWRAP1315
CBU/TWY120
CBU1014
CBU1014DB
CBU120
CBU1315
CBU150
CDB/CG060

CDB/CG075
CDB/CG075DB
CDB/CG090
CDB/CG100
CDB/CG1012
CDB/CG1012DB
CDB/CG1014
CDB/CG120
CDB/CG120DB
CDB/CG1215
CDB/CG1215DB
CDB/CG1315
CDB/CG1315DB
CDB/CG140
CDB/CG150
CDB/CG150DB
CDB/CG1815
CDB/CG1815DB
CDB/GC120
CDB/GC140
CDB/TWO090
CDB/TWR120
CDB/TWRAP090
CDB/TWRAP100
CDB140
CDB1815
CDB5075
CDG/CB060
CDG/CB075
CDG/CB075DB
CDG/CB090
CDG/CB100
CDG/CB1012DB
CDG/CB1015
CDG/CB120
CDG/CB120DB
CDG/CB1215DB
CDG/CB1315
CDG/CB1315DB
CDG/CB1815DB
CDG/TWO1215
CDG/TWO1315X
CDG/TWRAP060
CDG/TWRAP075
CDG/TWRAP090
CDG/TWRAP100
CDG/TWRAP100DB
CDG/TWRAP1014
CDG/TWRAP120
CDG/TWRAP120DB
CDG/TWRAP1214
CDG/TWRAP1215
CDG/TWRAP1315
CDG/TWRAP150
CDG/TWY1315
CDG075
CDG090
CDG100
CDG120
CDG1215
CDG140
CDG150
CDG1815
CG/CB050
CG/CB060

CG/CB075
CG/CB075DB
CG/CB090
CG/CB100
CG/CB100DB
CG/CB1012
CG/CB1014
CG/CB1014DB
CG/CB1075
CG/CB1075DB
CG/CB1090
CG/CB120
CG/CB1215
CG/CB1215X
CG/CB1315
CG/CB1315/P120
CG/CB1315DB
CG/CB1315X
CG/CB140
CG/CB140X
CG/CB150
CG/CB1715
CG/CB1715/F4
CG/CB1815
CG/CB1815/P72
CG/CB5045
CG/CBA120
CG/CBU075
CG/CBU090
CG/CBU100
CG/CBU100DB
CG/CBU1012
CG/CBU1014
CG/CBU1090
CG/CBU1215
CG/CBU1315DB
CG/CBU1315X
CG/PRO1215
CG/PRO1815
CG/TWO060
CG/TWO090
CG/TWO1012
CG/TWO1012DB
CG/TWO1014
CG/TWO1014DB
CG/TWO1075
CG/TWO1075DB
CG/TWO1090DB
CG/TWO120
CG/TWO1215
CG/TWO1215DB
CG/TWO1215PZDB
CG/TWO1315
CG/TWO140
CG/TWO1715
CG/TWO1715DB
CG/TWO1815
CG/TWO1815DB
CG/TWR060
CG/TWR090DB
CG/TWR100
CG/TWR100DB
CG/TWR1014
CG/TWR1090DB
CG/TWR1215PZDB

CG/TWR1315
CG/TWR1315PZDB
CG/TWR1715DB
CG/TWR1815PZDB
CG/TWRAP060
CG/TWRAP075
CG/TWRAP075DB
CG/TWRAP090
CG/TWRAP090DB
CG/TWRAP100
CG/TWRAP100DB
CG/TWRAP1012
CG/TWRAP1012DB
CG/TWRAP1014
CG/TWRAP1014DB
CG/TWRAP1075
CG/TWRAP1090
CG/TWRAP1090DB
CG/TWRAP120
CG/TWRAP120DB
CG/TWRAP1215
CG/TWRAP1215DB
CG/TWRAP1215PZDB
CG/TWRAP1315
CG/TWRAP1315DB
CG/TWRAP1315PZ
CG/TWRAP1315PZDB
CG/TWRAP140
CG/TWRAP140DB
CG/TWRAP150
CG/TWRAP1715DB
CG/TWRAP1815
CG/TWRAP1815/F4
CG/TWRAP1815DB
CG/TWRAP5075
CG/TWRAP5075DB
CG/TWRAPDRY060DB
CG/TWRAPDRY075
CG/TWRAPDRY090
CG/TWRAPDRY090DB
CG/TWRAPDRY100
CG/TWRAPDRY1012
CG/TWRAPDRY1014
CG/TWRAPDRY1075
CG/TWRAPDRY1090
CG/TWRAPDRY120
CG/TWRAPDRY120DB
CG/TWRAPDRY1215
CG/TWRAPDRY1315
CG/TWRAPDRY1315D
CG/TWRAPDRY1315X
CG/TWRAPDRY140
CG/TWRAPDRY150
CG/TWRAPDRY1715
CG/TWRAPDRY1815
CG/TWRAPDRY1815M
CG/TWY060
CG/TWY075DB
CG/TWY090
CG/TWY090DB
CG/TWY100
CG/TWY100DB
CG/TWY1012
CG/TWY1012DB
CG/TWY1090

CG/TWY1090DB
CG/TWY1215
CG/TWY1215PZDB
CG/TWY1315
CG/TWY1315DB
CG/TWY1815
CG/WB120
CG/WB1315
CG/WB1815
CG060
CG075
CG075DB
CG090
CG090/P150
CG100
CG100/P150
CG100DB
CG120
CG120DB
CG1215
CG1315
CG140
CG150
CG1715DB
CG1815DB
CG5075
CGP/CB100
CGP/CB120
CGP/CB1715
CGP/CB1815
CGP/CBU100
CGP/CBU1014
CGP/CBU1014DB
CGP/CBU1090
CGP/CBU1215
CGP/CBU1315
CGP/CBU140
CGP/CBU1815
CGP/TWO100
CGP/TWO1012
CGP/TWO1215
CGP/TWO1815
CGP/TWRAP060
CGP/TWRAP060DB
CGP/TWRAP075
CGP/TWRAP075DB
CGP/TWRAP090
CGP/TWRAP100
CGP/TWRAP1012
CGP/TWRAP1075
CGP/TWRAP120
CGP/TWRAP1215
CGP/TWRAP1315
CGP/TWRAP150
CGP/TWRAP1815
CGP/TWY075
CGP/TWY100
CGP/TWY1315
CGP/TWY1815
CGP1315
CGP150
CGX/CB075
CGX/CB075DB
CGX/CB090
CGX/CB100

	CGX/CB100DB CGX/CB1012 CGX/CB1012DB CGX/CB1014 CGX/CB1090 CGX/CB1090DB CGX/CB1215 CGX/CB1215DB CGX/CB1315 CGX/CB1315/P120 CGX/CB1315P120DB CGX/CB1715 CGX/CB1715DB CGX/CB1815 CGX/CB1815DB CGX/CB5075 CGX/CB5075DB CGX/CBU060 CGX/CBU060DB CGX/CBU100 CGX/CBU1012 CGX/CBU1014 CGX/CBU1014DB CGX/CBU1090 CGX/CBU1090DB CGX/CBU1215 CGX/CBU1315 CGX/CBU1315DB CGX/CBU1815 CGX/TWO1012DB CGX/TWO1090DB CGX/TWO1215PZDB CGX/TWO1315 CGX/TWR1090DB CGX/TWR1215PZDB CGX/TWR1715DB CGX/TWRAP075DB CGX/TWRAP090 CGX/TWRAP090DB CGX/TWRAP100 CGX/TWRAP100DB CGX/TWRAP1012 CGX/TWRAP1012DB CGX/TWRAP1090DB CGX/TWRAP1215 CGX/TWRAP1215PZDB CGX/TWRAP1315 CGX/TWRAP1315PZDB CGX/TWRAP1715DB CGX/TWRAP1815 CGX/TWRAP1815DB CGX/TWRAP5075 CGX/TWRAP5075DB CGX/TWRAPD100DB CGX/TWRAPD1215DB CGX/TWRAPD1315DB CGX/TWRAPDRY100 CGX/TWRAPDRY1215 CGX/TWRAPDRY1315 CGX/TWY090DB CGX/TWY1012DB CGX/TWY1090DB CGX/TWY1215PZDB CGX/TWY1315 CGX/TWY1315DB			
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CGX090
CGX100
CGX100DB
CGX120
CGX1715DB
REL340G/CBU100
REL340G/CBU1014
REL340G/CBU1215
REL340G/CBU1315
RELGRN/CB100
RELGRN/CB1050
RELGRN/CB1315
RELGRN/CB140
RELGRN/WB1815
WB/TDRY100DB
WB/TWO075
WB/TWO1012
WB/TWO1014
WB/TWO1014DB
WB/TWO1315
WB/TWRAP060
WB/TWRAP075
WB/TWRAP090
WB/TWRAP100
WB/TWRAP100DB
WB/TWRAP1012
WB/TWRAP1014DB
WB/TWRAP1075
WB/TWRAP1215
WB/TWRAP1215DB
WB/TWRAP1315
WB/TWRAP1815
WB/TWRAPDRY060
WB/TWRAPDRY090
WB/TWRAPDRY100
WB/TWRAPDRY120
WB/TWRAPDRY1315X
WB/TWRAPDRY150
WB/TWRAPDRY150F3
WB/TWY090
WB/TWY1014
WB/TWY1215
WB075
WB090
WB100
WB1014
WB120
WB140
CBA060
CBU140
CDG1315
CG/TWRAPDRY060
CGX/TWY1215
WB/TWRAPDRY1012
MC-CBA/TWRAP090
MC-CBA/TWRAP100
MC-CBA/TWRAP120
RELGRN/CBU100
RELGRN/CBU140
CG/CBU120
CGX/TWY090
CGX/TWY1012
CG/CBU1815
CB/TDRY075
CB/TDRY090

		CB/TDRY100 CB/TDRY060 CB/TDRY120 CGX/TWR1815			
Transportation Wrap Intended Purpose: Transportation Barrier Wrap	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB	GMDN: 13735		0849771000000000000009MK

TWRAP1014
TWRAP1090DB
TWRAP120
TWRAP1215
TWRAP1215DB
TWRAP1315
TWRAP1315DB
TWRAP140
TWRAP140DB
TWRAP150
TWRAP150DB
TWRAP1715
TWRAP1715DB
TWRAP1815
TWRAP1815DB
TWRAP5090
TWRAP5390
TWRAP7537
TWRAP75375
TWRAPDRY050
TWRAPDRY060
TWRAPDRY075
TWRAPDRY090
TWRAPDRY100
TWRAPDRY1012
TWRAPDRY1014
TWRAPDRY120
TWRAPDRY1315
TWRAPDRY140
TWRAPDRY1815
TWRAPDRY3015
TWRAPDRY3015SGL
TWRAPDRY5075
TWRAPDRY7560
TWRAPDRYOFFCUT
TWY075
TWY075DB
TWY090
TWY100
TWY100DB
TWY1012
TWY1014
TWY120
TWY1215
TWY1215DB
TWY1315
TWY1315DB
TWY140
TWY1715
TWY1715DB
TWY1815
CDBAG002G
H-THCOVER001
H-THCOVER002
H-THCOVER003
H-THOCOVER001
H-THOCOVER002
H-THOCOVER003
H-THRCOVER001
H-THRCOVER002
H-THRCOVER003
H-THYCOVER001
H-THYCOVER002
H-THYCOVER003
PC000700

		PC000800 PC000900 PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELLO01 TCOVER-YELLO02 TCOVER-YELLO03			
Transportation Wrap Intended Purpose: Transportation Barrier Wrap	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN: 13735		
Container Filters Intended Purpose: For use with sterilization containers.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153	GMDN: 60909	0849771000000000000010M4	

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01368
01369
01373
04111
1070020
26510
27320
27330
27340
27350
27360
55-291-01-04
61140
71140
71141
71194
91140
26515
27325
27335
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27365
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26510
ME01194
ME26515

		ME27325 ME27335 ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Tray Liners Intended Purpose: For use in sterilization of medical devices.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007 H-TLC008 H-TLC009 H-TLC010 H-TLC011 H-TLC012 H-TLC013 H-TLC078 H-TLC109 H-TLC110 H-TLC111 H-TLC119 H-TLC213 H-TLC214 H-TLC215 LIB1328 LIB250X320 LIB300X360 LIB300X500 LIB3025 LIB3050 LIB400X500 LINH3020 LINH3041 LINH4555 MILB002 MILB003 MILB004 MILB005 MILB006 MILB007 MILB008 MILB009 MILB011 MILB012	GMDN:60908	084977100000000000000011M6	

	MILB016 MILB017 MILB019 MILB020 MILB021 MILB022 MILB025 MILB027 MILB029 MILB056 MILB120X250 MILB130X230 MILB170X270 MILB250X300 MILB300X400 MILB305X450 MILB350x450 MILB375X600 MILB450X650 MILB500X900 PC002100 PC002200 PC008800 PC008900 PC009000 PC009100 PC009200 PC009400 PC009800 PC009900 PC010000 PC010200 PC010400 PC010700 PC010800 PC011200 PC011300 PC011400 PC011700 PC011800 PC013300 PC013600 TL-101-200 TL-202-500 TL-203-500 TL-204-500 TLC001 TLC002 TLC004 TLC005 TLC006 TLC007 TLC008 TLC009 TLC010 TLC011 TLC012 TLC013 TLC014 TLC017 TLC018 TLC019 TLC020 TLC022 TLC023			
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		TLC024 TLC027 TLC029R TLC030 TLC031 TLC034 TLC036 TLC045 TLC051 TLC052 TLC055 TLC060 TLC066 TLC069 TLC071 TLC072 TLC078 TLC079 TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300	GMDN:61664		

		PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Maintenance Oil Intended Purpose: Intended for use in lubricating medical devices.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	0849771000000000000012M8	
Chirol Ultra Intended Purpose: Cleaning solution for removing soils from metallic surfaces.	Chirol Ultra	02110	GMDN: 63385	084977100000000000000013MA	

We hereby appoint Medical Device Safety Service (MDSS)
 Schiffgraben 41
 D-30175 Hannover
 Germany

as the European Authorized Representative as defined in Article 2(32) of the MDR.

Conformity Assessment Route: Annex IV

Issued By:

Signature:



Date: 2021-12-28

Name: Coletta Cohara
Position: Director Quality and Regulatory Compliance
Place of Issue of Key Surgical LLC
DoC: 8101 Wallace Rd.
Eden Prairie, MN 55344
USA

DE - Konformitätserklärung

Wir, der Hersteller,

Key Surgical LLC
 8101 Wallace Rd.
 Eden Prairie, MN 55344
 USA

gewährleisten und bestätigen in alleiniger Verantwortung, dass die folgenden unsterilen (gemäß MDR), nicht wiederverwendbaren, nicht messenden Medizinprodukte der Klasse I die auf sie zutreffenden Bestimmungen der EU-Verordnung über Medizinprodukte 2017/745 (MDR) Anhang IV für Medizinprodukte erfüllen. Diese Produkte entsprechen der Verordnung über Medizinprodukte 2017/745, welche die Ausstellung der EU-Konformitätserklärung vorsieht. Alle unterstützenden Unterlagen werden in den Räumlichkeiten des Herstellers aufbewahrt.

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
Reinigungsbürsten	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	084977100000000000000001M3	Es gibt keine gemeinsamen, von der Europäischen Kommission im Rahmen der MDR festgelegten Spezifikationen, die für das Produkt von Key Surgical in dieser Erklärung gelten. Angewandte Normen sind in der technischen Dokumentation
	Verwendungszweck: Reinigung von Medizinprodukten	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336 09338 09339		

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		09340			on ausgewiesen.
		09341			
		09342			
		09343			
		09344			
		09345			
		09346			
		09365			
		09366			
		09380			
		09388			
		09499			
		09745			
		09746			
		09747			
		AT-12-062			
		AT-12-062-50			
		AT-12-087			
		AT-12-087-50			
		AT-12-105			
		AT-12-105-50			
		AT-12-118			
		AT-12-118-50			
		AT-12-125			
		AT-12-125-50			
		AT-12-131			
		AT-12-131-50			
		AT-12-158			
		AT-12-158-50			
		AT-12-197			
		AT-12-197-50			
		AT-12-250			
		AT-12-250-50			
		AT-12-276			
		AT-12-276-50			
		AT-12-375			
		AT-12-375-50			
		AT-12-440			
		AT-12-440-50			
		AT-18-062			
		AT-18-062-50			
		AT-18-087			
		AT-18-087-50			
		AT-18-105			
		AT-18-105-50			
		AT-18-118			
		AT-18-118-50			
		AT-18-125			
		AT-18-125-50			
		AT-18-131			
		AT-18-131-50			
		AT-18-158			
		AT-18-158-50			
		AT-18-197			
		AT-18-197-50			
		AT-18-250			
		AT-18-250-50			
		AT-18-276			
		AT-18-276-50			
		AT-18-375			
		AT-18-375-50			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		AT-18-440			
		AT-18-440-50			
		AT-24-062			
		AT-24-062-50			
		AT-24-087			
		AT-24-087-50			
		AT-24-105			
		AT-24-105-50			
		AT-24-118			
		AT-24-118-50			
		AT-24-125			
		AT-24-125-50			
		AT-24-131			
		AT-24-131-50			
		AT-24-158			
		AT-24-158-50			
		AT-24-197			
		AT-24-197-50			
		AT-24-250			
		AT-24-250-50			
		AT-24-276			
		AT-24-276-50			
		AT-24-375			
		AT-24-375-50			
		AT-24-440			
		AT-24-440-50			
		B-2100-50			
		BBR001			
		BBR002			
		BBR003			
		BR-04-003			
		BR-04-003-50			
		BR-04-080			
		BR-04-080-50			
		BR-06-039-50			
		BR-06-062			
		BR-06-062-50			
		BR-06-079			
		BR-06-079-50			
		BR-06-250			
		BR-06-250-50			
		BR-06-375			
		BR-06-375-50			
		BR-06-500			
		BR-06-500-50			
		BR-07-075			
		BR-07-075-50			
		BR-07-107			
		BR-07-107-50			
		BR-08-039			
		BR-08-039-50			
		BR-08-070			
		BR-08-070-50			
		BR-08-079			
		BR-08-079-50			
		BR-08-087			
		BR-08-087-50			
		BR-08-092			
		BR-08-092-50			
		BR-08-105			
		BR-08-105-50			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		BR-08-118			
		BR-08-118-50			
		BR-08-131			
		BR-08-131-50			
		BR-08-144			
		BR-08-144-50			
		BR-08-158			
		BR-08-158-50			
		BR-08-250			
		BR-08-250-50			
		BR-08-440			
		BR-08-440-50			
		BR-08-630			
		BR-08-630-50			
		BR-12-079			
		BR-12-079-50			
		BR-12-118			
		BR-12-118-50			
		BR-12-158			
		BR-12-158-50			
		BR-12-197			
		BR-12-197-50			
		BR-12-236			
		BR-12-236-50			
		BR-16-197			
		BR-16-197-50			
		BR-16-236			
		BR-16-236-50			
		BR-16-276			
		BR-16-276-50			
		BR-16-393			
		BR-16-393-50			
		BR-16-443			
		BR-16-443-50			
		BR-16-472			
		BR-16-472-50			
		BR-16-591			
		BR-16-591-50			
		BR-16-787			
		BR-16-787-50			
		BR-18-039			
		BR-18-039-50			
		BR-18-062			
		BR-18-062-50			
		BR-18-070			
		BR-18-070-50			
		BR-18-087			
		BR-18-087-50			
		BR-18-105			
		BR-18-105-50			
		BR-18-125			
		BR-18-125-50			
		BR-18-158			
		BR-18-158-50			
		BR-18-197			
		BR-18-197-50			
		BR-18-250			
		BR-18-250-50			
		BR-18-393			
		BR-18-393-50			
		BR-18-591-50			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		BR-18-880-50			
		BR-2300			
		BR-24-070-50			
		BR-24-080-50			
		BR-24-098-50			
		BR-24-197-50			
		BR-24-200-50			
		BR-24-236-50			
		BR-24-276-50			
		BR-24-312-50			
		BR-24-375-50			
		BR-24-393-50			
		BR-24-425-50			
		BR-24-440-50			
		BR-24-443-50			
		BR-24-880-50			
		BR-4199			
		BR-4299			
		BR-4399			
		BR-4499			
		BR-4599			
		BR-4699			
		BR-4799			
		BR-4899			
		BR-4999			
		BR-5099			
		BR-5199C			
		BR-6099			
		BR-8110			
		BR-8110-50			
		BR-8115			
		BR-8115-50			
		BR-8210			
		BR-8210-50			
		BR-8310			
		BR-8310-50			
		BR-8315			
		BR-8315-50			
		BR-8410			
		BR-8410-50			
		BZ-06-2550			
		BZ-06-2550-50			
		BZ-08-125			
		BZ-08-125-50			
		BZ-10-050			
		BZ-10-050-50			
		BZ-12-062			
		BZ-12-062-50			
		BZ-12-087			
		BZ-12-087-50			
		BZ-12-098			
		BZ-12-098-50			
		BZ-12-125			
		BZ-12-125-50			
		BZ-12-158			
		BZ-12-158-50			
		BZ-16-250			
		BZ-16-250-50			
		BZ-18-062			
		BZ-18-062-50			
		BZ-18-079			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		BZ-18-079-50			
		BZ-18-1000			
		BZ-18-1000-50			
		BZ-18-105			
		BZ-18-105-50			
		BZ-18-125			
		BZ-18-125-50			
		BZ-18-131			
		BZ-18-131-50			
		BZ-18-144			
		BZ-18-144-50			
		BZ-18-1543			
		BZ-18-1543-50			
		BZ-18-158			
		BZ-18-158-50			
		BZ-18-197			
		BZ-18-197-50			
		BZ-18-236			
		BZ-18-236-50			
		BZ-18-250			
		BZ-18-250-50			
		BZ-18-312			
		BZ-18-312-50			
		BZ-18-354			
		BZ-18-354-50			
		BZ-18-393			
		BZ-18-393-50			
		BZ-18-433			
		BZ-18-433-50			
		BZ-18-472			
		BZ-18-472-50			
		BZ-24-125			
		BZ-24-125-50			
		FLEX001			
		FLEX002			
		FLEX003			
		FLEX004			
		FLEX005			
		FLEX006			
		FLEX007			
		FLEX007A			
		FLEX007B			
		FLEX011			
		FLEX021			
		FLEX022			
		FLEX023			
		FLEX024			
		FLEX028			
		FLEX033			
		FLEXSAMP			
		FT-12-197			
		FT-12-197-50			
		FT-12-250			
		FT-12-250-50			
		FT-12-276			
		FT-12-276-50			
		FT-12-375			
		FT-12-375-50			
		FT-12-440			
		FT-12-440-50			
		FT-12-500			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		FT-12-500-50 FT-18-197 FT-18-197-50 FT-18-250 FT-18-250-50 FT-18-276 FT-18-276-50 FT-18-375 FT-18-375-50 FT-18-440 FT-18-440-50 FT-18-500 FT-18-500-50 FT-24-197 FT-24-197-50 FT-24-250 FT-24-250-50 FT-24-276 FT-24-276-50 FT-24-375 FT-24-375-50 FT-24-440 FT-24-440-50 FT-24-500 FT-24-500-50 H-FLEX001 H-FLEX002 H-FLEX003 H-FLEX004 H-FLEX005 H-FLEX006 H-FLEX007 H-FLEX007A H-FLEX008H H-FLEX009 H-FLEX010 H-FLEX021 H-FLEX022 H-FLEX023 H-FLEX024 H-FLEX025 H-FLEX026 H-FLEX027 H-FLEX033 H-FLEX034 H-FLEX035 H-FLEXSAMP MED100.10 MED100.11 MED100.12 MED100.13 MED100.14 MED100.15 MED100.16 MED100.17 MED100.18 MED100.19 MED100.20 MED100.21 MED100.22 MED100.23			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		MED100.24			
		MED100.25			
		MED100.26			
		MED100.27			
		MED100.28			
		MED100.29			
		MED100.30			
		MED100.31			
		MED100.32			
		MED100.48			
		MED100.49			
		MED100.52			
		MED100.57			
		MED100.58			
		MED100.59			
		MED100.61			
		MED100.62			
		MJ-370			
		MJ-370C-1			
		PC-100C			
		PC-112C			
		PC-200C			
		PC-212C			
		PC-300P			
		PC-306P			
		PC-312P			
		PC-400P			
		PC-412P			
		PC-503			
		PC-512			
		PC-515			
		PP-16-039			
		PP-16-039-50			
		PP-16-062			
		PP-16-062-50			
		PP-16-087			
		PP-16-087-50			
		PP-16-105			
		PP-16-105-50			
		PP-16-125			
		PP-16-125-50			
		PP-16-158			
		PP-16-158-50			
		PP-18-197			
		PP-18-197-50			
		PP-18-250			
		PP-18-250-50			
		PP-18-393			
		PP-18-393-50			
		PP-18-591			
		PP-18-591-50			
		PP-18-750			
		PP-18-750-50			
		PP-22-039-50			
		PP-22-062-50			
		PP-22-087-50			
		PP-22-105-50			
		PP-22-125-50			
		PP-22-158-50			
		PP-22-197-50			
		PP-24-250-50			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		PT-28-118-50 PT-28-197-50 BR-06-039 PP-22-039 PP-22-062 PP-22-087 PP-22-105 PP-22-125 PP-22-158 PP-22-197 PP-24-250 PT-28-118 PT-28-197 FLEX008 FLEX009 FLEX025 FLEX026 BR-18-591 BR-18-880 BR-24-070 BR-24-080 BR-24-098 BR-24-197 BR-24-200 BR-24-236 BR-24-276 BR-24-312 BR-24-375 BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4 96281.7 MED100.98			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		26474 26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197 BR-31-276 BR-3201 BR-3201-50 BR-4140			
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600			
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325			
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50 BR-075-24 BR-075-24-50 BR-075-32 BR-075-32-50 BR-075-42 BR-075-42-50 BR-075-99 BR-100-18 BR-100-18-50 BR-100-24 BR-100-24-50 BR-100-32 BR-100-32-50 BR-100-42 BR-100-42-50 BR-100-99, BR-150-18 BR-150-18-50 BR-150-24 BR-150-24-50 BR-150-32 BR-150-32-50 BR-150-42 BR-150-42-50 BR-150-99 BR-200-18 BR-200-18-50			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		BR-200-24 BR-200-24-50 BR-200-32 BR-200-32-50 BR-200-42 BR-200-42-50 BR-200-99 BR-3030 BR-3030-50 BR-3035 BR-3035-50 BR-3040 BR-3040-50 BR-3202 BR-3202-50 BR-3299 BR-3300 BR-3305 BR-3307 BR-3308 BR-3308-50 BR-3309 BR-3309-50 BR-3310 BR-3310-50 BR-3320 BR-3320-50 BR-3330 BR-3330-50 BR-3340 BR-3340-50 BR-3399 BR-3410 BR-3410-50 BR-3420 BR-3420-50 BR-3701 BR-3702 BR-3703 BR-3711-100 BR-3711-50 BR-3799-50 BR-3711			
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21-134 GMDN: 38835		
Spülkanülen Verwendungszweck: Zur Verwendung bei der Wundspülung vorgesehen.	Key Surgical Cannulas (non-sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15-206 GMDN: 62389	0849771000000000000002M5	
	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06-01, 01800, 3-06-02, I3-06-02, 01801, 3-06-03, I3-06-03, 01802, 3-06-04, I3-06-04, 01803, 3-06-05, I3-06-05, 01804,			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
<p>Instrumentenschutzhilfen</p> <p>Verwendungszweck: Zur Abdeckung und zum Schutz medizinischer Instrumente vorgesehen.</p>		<p>3-06-07, I3-06-07, 01805, 3-11-01, I3-11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11-03, 01828, 3-11-04, I3-11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12-01, 01838, 3-12-02, I3-12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, I3-12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12-09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10-04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09-03, 01814, 3-09-04, I3-09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09-08, I3-09-08, 01472, 01473, 3-09-09, 01474, 01475, 01494, 3-09-10, 3-24-98, 3-24-99, 3-48-50, 3-80-03, 3-60-01, 3-60-02, 3-60-03, 3-60-04, 3-60-05, 3-60-06, 3-60-07, 3-60-08, 3-60-09, 3-60-10, 3-60-11, 01471, 01476, 01477, 01469, 01470, 01478, 01479, 01492, 01496, 01499, 3-01-01, 01865, 3-01-02, 01890, 3-01-03, 01866, 3-01-04, 01867, 3-01-05, 01891, 3-01-06, 01892, 3-02-01, 01876, 3-02-02, 3-02-03, 01877, 3-02-04, 01878, 3-02-06, 3-03-01, 01871, 3-03-02, 01872, 3-03-03, 01873, 3-03-04, 01874, 3-03-05, 01875, 3-03-06, 3-</p>	<p>UMDNS: 16-222 GMDN: 63247</p>	<p>0849771000000000000003M7</p>	

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		04-01, 01484, 3-04-02, 01485, 3-04-03, 01486, 3-04-04, 01487, 3-04-05, 01488, 3-04-06, 01489, 3-08-01, 01460, 3-08-02, 01461, 3-08-03, 01462, 3-08-04, 01463, 3-08-05, 01464, 3-08-06, 01465, 3-09-01, 3-09-02S, 3-15-01, 01868, 3-15-02, 01869, 3-15-03, 01870, 3-15-04, 01884, 3-15-05, 01885, 3-15-06, 01886, 3-21-03, 3-24-06, 3-24-20, , 3-42-95, 3-44-01, 3-44-02, 3-44-03, 3-44-04, 3-44-05, 3-44-06, 3-44-96, 3-44-97, 3-48-01,, 3-48-02, 3-48-03, 3-48-04, 3-48-05, 3-48-06, ,3-48-61, 3-48-62, 3-48-94, 3-48-95, 3-74-05, 3-74-06, I3-03-01, I3-03-02, I3-03-03, I3-04-01, I3-04-02, I3-04-03, I3-04-04, I3-04-05, I3-04-06, I3-08-01, I3-08-02, I3-08-03, I3-08-04, I3-08-05, I3-08-06,3-03-11, 3-03-12, 3-03-13, 3-03-15, 3-04-11, 01806, 3-04-12, 01807, 3-04-13, 01808, 01809, 3-04-17, 01811, 3-04-18, 01812, 3-04-19, 01813, 3-08-11, 3-08-12, 3-08-13, 3-08-15, 3-08-17, 3-08-18, 3-08-19, 3-24-11, 3-24-13, 3-24-15, 3-24-17, 3-44-11, 3-44-12, 3-44-13, 3-44-15, 3-44-16, 3-44-17, 3-44-18, 3-44-19, 3-48-11, 3-48-12, 3-48-13, 3-48-15, 3-48-16,3-48-17, 3-48-18, 3-48-19, 3-74-11, 3-74-15, 3-78-11, I3-04-11, I3-04-12, I3-04-13, I3-04-15, I3-04-18, 3-04-07, 01480, 3-04-08, 01481, 3-04-09, 01482, 01810, 3-08-07, 01466, 3-08-08, 01467, 3-08-09, 01468, 3-15-07, 01887, 3-15-08, 01888, 3-15-09, 01889, 3-24-08, 3-24-09, 3-44-07, 3-44-08, 3-44-09, 3-48-07, 3-48-08, 3-48-09, 3-74-07, 3-74-09, I3-04-07, I3-04-08, I3-04-09,			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
K-Draht und Nagelabdeckungen Verwendungszweck: Zum Schutz und Abdecken von K-Drähten und Nägeln.		I3-08-07, I3-08-08, I3-08-09, 3-01-07, 3-01-08, 01824, 3-01-09, 3-02-07, 01879, 3-02-08, 3-02-09, 3-03-07, 3-03-08, 3-03-09, 3-16-05, 3-16-06, 3-16-07, 3-16-08, 01821, 3-16-09, 30000, 30001, 30002, 30003, 30004, 30005, 30006, 30007, 30008, 30009, 30010, 30012, 30013, 30014, 30015, 30016, 30017, 01850, 01851, 01852, 01853, 01854, TP-09-11, TP-09-12, TP-09-13, 3-02-05, 3-04-15, 3-06-50, 3-08-09, 3-08-100, 3-11-01, 01826			
	Key Surgical Instrument Tip Protectors	PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457			
	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
Instrumentensterilisationsschale	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS:12-143 GMDN: 13730	0849771000000000000004M9	
	Key Surgical Finger Mat	FM-1810			
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50 DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			
		Key Surgical Scope Baskets			
Verwendungszweck: Schutz der Geräte bei der Reinigung, Sterilisation und Lagerung.					

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
Schalen-Eckenschoner Verwendungszweck: zum Schutz der Ecken von Sterilisationsschalen und Sterilisationsfolie	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15-907 GMDN: 63494 & 65133	084977100000000000000005MB	
Klebstoffentferner Verwendungszweck: Lösung zur Entfernung von Klebstoffrückständen von medizinischen Instrumenten	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN:64150	084977100000000000000006MD	
Heißluftfolie Verwendungszweck: zur Verwendung bei Heißluftsterilisationsmethoden vorgesehen	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735	084977100000000000000007MF	
Sterilisationsverpackung Verwendungszweck: Sterilbarrierenverpackung	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100 CB/TWO120 CB/TWR120 CB/TWRAP060 CB/TWRAP075 CB/TWRAP090 CB/TWRAP100 CB/TWRAP1012 CB/TWRAP120 CB/TWRAP1315 CB/TWRAP1315X CB/TWRAP150 CB/TWRAP150F3W	UMDNS: GMDN: 13735	084977100000000000000008MH	

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CB/TWRAP18135 CB/TWRAP1815 CB/TWRAP5075 CB/TWRAPDRY050 CB/TWRAPDRY060 CB/TWRAPDRY075 CB/TWRAPDRY090 CB/TWRAPDRY100 CB/TWRAPDRY120 CB/TWRAPDRY1315X CB/TWRAPDRY140 CB/TWY100 CB/TWY120 CB030 CB050 CB060 CB075 CB090 CB100 CB100DB CB1012 CB1014 CB120 CB120DB CB1315 CB1315DB CB140 CB150 CB1540 CB1715 CB1715DB CB1815 CB1815DB CBA/TWRAP120 CBA/TWRAP140 CBA050 CBA075 CBA090 CBA100 CBA120 CBA1415 CBU/TWRAP100 CBU/TWRAP1215 CBU/TWRAP1315 CBU/TWY120 CBU1014 CBU1014DB CBU120 CBU1315 CBU150 CDB/CG060 CDB/CG075 CDB/CG075DB CDB/CG090 CDB/CG100 CDB/CG1012 CDB/CG1012DB CDB/CG1014 CDB/CG120 CDB/CG120DB CDB/CG1215			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CDB/CG1215DB CDB/CG1315 CDB/CG1315DB CDB/CG140 CDB/CG150 CDB/CG150DB CDB/CG1815 CDB/CG1815DB CDB/GC120 CDB/GC140 CDB/TWO090 CDB/TWR120 CDB/TWRAP090 CDB/TWRAP100 CDB140 CDB1815 CDB5075 CDG/CB060 CDG/CB075 CDG/CB075DB CDG/CB090 CDG/CB100 CDG/CB1012DB CDG/CB1015 CDG/CB120 CDG/CB120DB CDG/CB1215DB CDG/CB1315 CDG/CB1315DB CDG/CB1815DB CDG/TWO1215 CDG/TWO1315X CDG/TWRAP060 CDG/TWRAP075 CDG/TWRAP090 CDG/TWRAP100 CDG/TWRAP100DB CDG/TWRAP1014 CDG/TWRAP120 CDG/TWRAP120DB CDG/TWRAP1214 CDG/TWRAP1215 CDG/TWRAP1315 CDG/TWRAP150 CDG/TWY1315 CDG075 CDG090 CDG100 CDG120 CDG1215 CDG140 CDG150 CDG1815 CG/CB050 CG/CB060 CG/CB075 CG/CB075DB CG/CB090 CG/CB100 CG/CB100DB CG/CB1012			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CG/CB1014 CG/CB1014DB CG/CB1075 CG/CB1075DB CG/CB1090 CG/CB120 CG/CB1215 CG/CB1215X CG/CB1315 CG/CB1315/P120 CG/CB1315DB CG/CB1315X CG/CB140 CG/CB140X CG/CB150 CG/CB1715 CG/CB1715/F4 CG/CB1815 CG/CB1815/P72 CG/CB5045 CG/CBA120 CG/CBU075 CG/CBU090 CG/CBU100 CG/CBU100DB CG/CBU1012 CG/CBU1014 CG/CBU1090 CG/CBU1215 CG/CBU1315DB CG/CBU1315X CG/PRO1215 CG/PRO1815 CG/TWO060 CG/TWO090 CG/TWO1012 CG/TWO1012DB CG/TWO1014 CG/TWO1014DB CG/TWO1075 CG/TWO1075DB CG/TWO1090DB CG/TWO120 CG/TWO1215 CG/TWO1215DB CG/TWO1215PZDB CG/TWO1315 CG/TWO140 CG/TWO1715 CG/TWO1715DB CG/TWO1815 CG/TWO1815DB CG/TWR060 CG/TWR090DB CG/TWR100 CG/TWR100DB CG/TWR1014 CG/TWR1090DB CG/TWR1215PZDB CG/TWR1315 CG/TWR1315PZDB			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CG/TWR1715DB CG/TWR1815PZDB CG/TWRAP060 CG/TWRAP075 CG/TWRAP075DB CG/TWRAP090 CG/TWRAP090DB CG/TWRAP100 CG/TWRAP100DB CG/TWRAP1012 CG/TWRAP1012DB CG/TWRAP1014 CG/TWRAP1014DB CG/TWRAP1075 CG/TWRAP1090 CG/TWRAP1090DB CG/TWRAP120 CG/TWRAP120DB CG/TWRAP1215 CG/TWRAP1215DB CG/TWRAP1215PZDB CG/TWRAP1315 CG/TWRAP1315DB CG/TWRAP1315PZ CG/TWRAP1315PZDB CG/TWRAP140 CG/TWRAP140DB CG/TWRAP150 CG/TWRAP1715DB CG/TWRAP1815 CG/TWRAP1815/F4 CG/TWRAP1815DB CG/TWRAP5075 CG/TWRAP5075DB CG/TWRAPDRY060DB CG/TWRAPDRY075 CG/TWRAPDRY090 CG/TWRAPDRY090DB CG/TWRAPDRY100 CG/TWRAPDRY1012 CG/TWRAPDRY1014 CG/TWRAPDRY1075 CG/TWRAPDRY1090 CG/TWRAPDRY120 CG/TWRAPDRY120DB CG/TWRAPDRY1215 CG/TWRAPDRY1315 CG/TWRAPDRY1315D CG/TWRAPDRY1315X CG/TWRAPDRY140 CG/TWRAPDRY150 CG/TWRAPDRY1715 CG/TWRAPDRY1815 CG/TWRAPDRY1815M CG/TWY060 CG/TWY075DB CG/TWY090 CG/TWY090DB CG/TWY100 CG/TWY100DB CG/TWY1012			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CG/TWY1012DB CG/TWY1090 CG/TWY1090DB CG/TWY1215 CG/TWY1215PZDB CG/TWY1315 CG/TWY1315DB CG/TWY1815 CG/WB120 CG/WB1315 CG/WB1815 CG060 CG075 CG075DB CG090 CG090/P150 CG100 CG100/P150 CG100DB CG120 CG120DB CG1215 CG1315 CG140 CG150 CG1715DB CG1815DB CG5075 CGP/CB100 CGP/CB120 CGP/CB1715 CGP/CB1815 CGP/CBU100 CGP/CBU1014 CGP/CBU1014DB CGP/CBU1090 CGP/CBU1215 CGP/CBU1315 CGP/CBU140 CGP/CBU1815 CGP/TWO100 CGP/TWO1012 CGP/TWO1215 CGP/TWO1815 CGP/TWRAP060 CGP/TWRAP060DB CGP/TWRAP075 CGP/TWRAP075DB CGP/TWRAP090 CGP/TWRAP100 CGP/TWRAP1012 CGP/TWRAP1075 CGP/TWRAP120 CGP/TWRAP1215 CGP/TWRAP1315 CGP/TWRAP150 CGP/TWRAP1815 CGP/TWY075 CGP/TWY100 CGP/TWY1315 CGP/TWY1815			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CGP1315 CGP150 CGX/CB075 CGX/CB075DB CGX/CB090 CGX/CB100 CGX/CB100DB CGX/CB1012 CGX/CB1012DB CGX/CB1014 CGX/CB1090 CGX/CB1090DB CGX/CB1215 CGX/CB1215DB CGX/CB1315 CGX/CB1315/P120 CGX/CB1315P120DB CGX/CB1715 CGX/CB1715DB CGX/CB1815 CGX/CB1815DB CGX/CB5075 CGX/CB5075DB CGX/CBU060 CGX/CBU060DB CGX/CBU100 CGX/CBU1012 CGX/CBU1014 CGX/CBU1014DB CGX/CBU1090 CGX/CBU1090DB CGX/CBU1215 CGX/CBU1315 CGX/CBU1315DB CGX/CBU1815 CGX/TWO1012DB CGX/TWO1090DB CGX/TWO1215PZDB CGX/TWO1315 CGX/TWR1090DB CGX/TWR1215PZDB CGX/TWR1715DB CGX/TWRAP075DB CGX/TWRAP090 CGX/TWRAP090DB CGX/TWRAP100 CGX/TWRAP100DB CGX/TWRAP1012 CGX/TWRAP1012DB CGX/TWRAP1090DB CGX/TWRAP1215 CGX/TWRAP1215PZDB CGX/TWRAP1315 CGX/TWRAP1315PZDB CGX/TWRAP1715DB CGX/TWRAP1815 CGX/TWRAP1815DB CGX/TWRAP5075 CGX/TWRAP5075DB CGX/TWRAPD100DB CGX/TWRAPD1215DB			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CGX/TWRAPD1315DB CGX/TWRAPDRY100 CGX/TWRAPDRY1215 CGX/TWRAPDRY1315 CGX/TWY090DB CGX/TWY1012DB CGX/TWY1090DB CGX/TWY1215PZDB CGX/TWY1315 CGX/TWY1315DB CGX090 CGX100 CGX100DB CGX120 CGX1715DB REL340G/CBU100 REL340G/CBU1014 REL340G/CBU1215 REL340G/CBU1315 RELGRN/CB100 RELGRN/CB1050 RELGRN/CB1315 RELGRN/CB140 RELGRN/WB1815 WB/TDRY100DB WB/TWO075 WB/TWO1012 WB/TWO1014 WB/TWO1014DB WB/TWO1315 WB/TWRAP060 WB/TWRAP075 WB/TWRAP090 WB/TWRAP100 WB/TWRAP100DB WB/TWRAP1012 WB/TWRAP1014DB WB/TWRAP1075 WB/TWRAP1215 WB/TWRAP1215DB WB/TWRAP1315 WB/TWRAP1815 WB/TWRAPDRY060 WB/TWRAPDRY090 WB/TWRAPDRY100 WB/TWRAPDRY120 WB/TWRAPDRY1315X WB/TWRAPDRY150 WB/TWRAPDRY150F3 WB/TWY090 WB/TWY1014 WB/TWY1215 WB075 WB090 WB100 WB1014 WB120 WB140 CBA060 CBU140 CDG1315			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		CG/TWRAPDRY060 CGX/TWY1215 WB/TWRAPDRY1012 MC-CBA/TWRAP090 MC-CBA/TWRAP100 MC-CBA/TWRAP120 RELGRN/CBU100 RELGRN/CBU140 CG/CBU120 CGX/TWY090 CGX/TWY1012 CG/CBU1815 CB/TDRY075 CB/TDRY090 CB/TDRY100 CB/TDRY060 CB/TDRY120 CGX/TWR1815			
Transportverpackung Verwendungszweck: Transportbarrierenverpackung	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014	GMDN: 13735	0849771000000000000009MK	

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB TWRAP1014 TWRAP1090DB TWRAP120 TWRAP1215 TWRAP1215DB TWRAP1315 TWRAP1315DB TWRAP140 TWRAP140DB TWRAP150 TWRAP150DB TWRAP1715 TWRAP1715DB TWRAP1815 TWRAP1815DB TWRAP5090 TWRAP5390 TWRAP7537 TWRAP75375 TWRAPDRY050 TWRAPDRY060 TWRAPDRY075 TWRAPDRY090 TWRAPDRY100 TWRAPDRY1012 TWRAPDRY1014 TWRAPDRY120 TWRAPDRY1315 TWRAPDRY140 TWRAPDRY1815 TWRAPDRY3015 TWRAPDRY3015SGL TWRAPDRY5075 TWRAPDRY7560 TWRAPDRYOFFCUT TWY075 TWY075DB TWY090 TWY100 TWY100DB TWY1012 TWY1014 TWY120			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		TWY1215 TWY1215DB TWY1315 TWY1315DB TWY140 TWY1715 TWY1715DB TWY1815 CDBAG002G H-THCOVER001 H-THCOVER002 H-THCOVER003 H-THOCOVER001 H-THOCOVER002 H-THOCOVER003 H-THRCOVER001 H-THRCOVER002 H-THRCOVER003 H-THYCOVER001 H-THYCOVER002 H-THYCOVER003 PC000700 PC000800 PC000900 PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Transportverpackung Verwendungszweck: Transportbarrierenverpackung	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004	GMDN: 13735		

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400			
Behälterfilter Verwendungszweck: Zur Verwendung mit Sterilisationsbehältern.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157 01158 01167 01168 01181 01183 01186 01188 01189 01194 01196 01198 01300 01304 01306 01312 01314 01315 01317 01318 01319 01321 01322 01323 01327 01330 01331 01332 01346 01347 01348 01350 01355 01356 01363	GMDN: 60909	0849771000000000000010M4	

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		01365 01366 01367 01368 01369 01373 04111 1070020 26510 27320 27330 27340 27350 27360 55-291-01-04 61140 71140 71141 71194 91140 26515 27325 27335 27345 27355 27365 91140 26510 ME01194 ME26515 ME27325 ME27335 ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Schutzfolien für Schalen Verwendungszweck: Zur Verwendung bei der Sterilisation von Medizinprodukten.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007	GMDN: 60908	0849771000000000000011M6	

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		H-TLC008			
		H-TLC009			
		H-TLC010			
		H-TLC011			
		H-TLC012			
		H-TLC013			
		H-TLC078			
		H-TLC109			
		H-TLC110			
		H-TLC111			
		H-TLC119			
		H-TLC213			
		H-TLC214			
		H-TLC215			
		LIB1328			
		LIB250X320			
		LIB300X360			
		LIB300X500			
		LIB3025			
		LIB3050			
		LIB400X500			
		LINH3020			
		LINH3041			
		LINH4555			
		MILB002			
		MILB003			
		MILB004			
		MILB005			
		MILB006			
		MILB007			
		MILB008			
		MILB009			
		MILB011			
		MILB012			
		MILB016			
		MILB017			
		MILB019			
		MILB020			
		MILB021			
		MILB022			
		MILB025			
		MILB027			
		MILB029			
		MILB056			
		MILB120X250			
		MILB130X230			
		MILB170X270			
		MILB250X300			
		MILB300X400			
		MILB305X450			
		MILB350x450			
		MILB375X600			
		MILB450X650			
		MILB500X900			
		PC002100			
		PC002200			
		PC008800			
		PC008900			
		PC009000			
		PC009100			
		PC009200			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		PC009400			
		PC009800			
		PC009900			
		PC010000			
		PC010200			
		PC010400			
		PC010700			
		PC010800			
		PC011200			
		PC011300			
		PC011400			
		PC011700			
		PC011800			
		PC013300			
		PC013600			
		TL-101-200			
		TL-202-500			
		TL-203-500			
		TL-204-500			
		TLC001			
		TLC002			
		TLC004			
		TLC005			
		TLC006			
		TLC007			
		TLC008			
		TLC009			
		TLC010			
		TLC011			
		TLC012			
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		TLC014			
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		TLC023			
		TLC024			
		TLC027			
		TLC029R			
		TLC030			
		TLC031			
		TLC034			
		TLC036			
		TLC045			
		TLC051			
		TLC052			
		TLC055			
		TLC060			
		TLC066			
		TLC069			
		TLC071			
		TLC072			
		TLC078			
		TLC079			
		TLC081			
		TLC085			
		TLC086			
		TLC087			
		TLC095			

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300 PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045	GMDN:61664		

Produktfamilie	Handelsname des Produkts	Item Number	Produktcode(s)	Basic UDI-DI	Allgemeine Spezifikationen
		SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Wartungsöl Verwendungszweck: Zur Verwendung bei der Schmierung von Medizinprodukten.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	0849771000000000000012M8	
Chirol Ultra Verwendungszweck: Reinigungslösung zur Entfernung von Verschmutzungen von Metallflächen.	Chirol Ultra	02110	GMDN: 63385	0849771000000000000013MA	

Hiermit ernennen wir **Medical Device Safety Service (MDSS)**
Schiffgraben 41
D-30175 Hannover
Deutschland

zum autorisierten Vertreter für Europa im Sinne von Artikel 2 (32) der MDR.

Route der Konformitätsbeurteilung: Anhang IV

Herausgegeben von:

Unterschrift:



Datum: 2021-12-28

Name:

Coletta Cohara

Position:

Direktor, Qualitätssicherung und Einhaltung gesetzlicher Bestimmungen

DoC ausgestellt in:

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

ES - Declaración de conformidad

Nosotros, el fabricante,

Key Surgical LLC
 8101 Wallace Rd.
 Eden Prairie, MN 55344
 USA

garantizamos y declaramos con responsabilidad exclusiva, que los siguientes dispositivos médicos de Clase I estériles (según el Reglamento para Dispositivos Médicos [Medical Devices Regulations, MDR]), no reutilizables y que no se usan para mediciones cumplen con las disposiciones del Reglamento 2017/745 (MDR) del Anexo IV para Dispositivos Médicos de las UE, que se aplica a ellos. Estos dispositivos cumplen con el Reglamento para Dispositivos Médicos 2017/745 que establece la emisión de la declaración de conformidad de la UE. Toda la documentación de respaldo se conserva en virtud de las premisas del fabricante.

Familia de productos	Nombre comercial del producto	Item Number	Código(s) del producto	UDI-DI básico	Especificaciones comunes
Cepillos de limpieza Fin previsto: limpieza de dispositivos médicos	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	084977100000000000000001M3	No hay especificaciones comunes establecidas por la Comisión Europea en virtud de MDR que se apliquen al producto de Key Surgical en esta Declaración. Las normas reconocidas vigentes se identifican en la documentación técnica.
	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336 09338	UMDNS: 21-134 GMDN: 34878 y 38835		

09339
09340
09341
09342
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09365
09366
09380
09388
09499
09745
09746
09747
AT-12-062
AT-12-062-50
AT-12-087
AT-12-087-50
AT-12-105
AT-12-105-50
AT-12-118
AT-12-118-50
AT-12-125
AT-12-125-50
AT-12-131
AT-12-131-50
AT-12-158
AT-12-158-50
AT-12-197
AT-12-197-50
AT-12-250
AT-12-250-50
AT-12-276
AT-12-276-50
AT-12-375
AT-12-375-50
AT-12-440
AT-12-440-50
AT-18-062
AT-18-062-50
AT-18-087
AT-18-087-50
AT-18-105
AT-18-105-50
AT-18-118
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AT-18-125
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AT-18-131
AT-18-131-50
AT-18-158
AT-18-158-50
AT-18-197
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AT-18-250
AT-18-250-50
AT-18-276
AT-18-276-50
AT-18-375
AT-18-375-50
AT-18-440
AT-18-440-50
AT-24-062

AT-24-062-50
AT-24-087
AT-24-087-50
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AT-24-118
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AT-24-131
AT-24-131-50
AT-24-158
AT-24-158-50
AT-24-197
AT-24-197-50
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PC-112C
PC-200C
PC-212C

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PC-312P
PC-400P
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BR-24-236
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BR-24-312

		BR-24-375 BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4 96281.7 MED100.98 26474 26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197			

		BR-31-276 BR-3201 BR-3201-50 BR-4140		
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600		
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325		
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50 BR-075-24		

BR-075-24-50
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BR-075-32-50
BR-075-42
BR-075-42-50
BR-075-99
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BR-3701
BR-3702
BR-3703

		BR-3711-100 BR-3711-50 BR-3799-50 BR-3711			
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21-134 GMDN: 38835		
Cánulas de irrigación Fin previsto: indicado para su uso en la irrigación de heridas.	Key Surgical Cannulas (non-sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15-206 GMDN: 62389	084977100000000000000002M5	
Protectores de instrumentos Fin previsto: Destinados a cubrir y proteger los instrumentos médicos.	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06-01, 01800, 3-06-02, I3-06-02, 01801, 3-06-03, I3-06-03, 01802, 3-06-04, I3-06-04, 01803, 3-06-05, I3-06-05, 01804, 3-06-07, I3-06-07, 01805, 3-11-01, I3-11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11-03, 01828, 3-11-04, I3-11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12-01, 01838, 3-12-02, I3-12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, I3-12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12-09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10-04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09-03, 01814, 3-09-04, I3-09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09-08, I3-09-08, 01472, 01473, 3-09-09,	UMDNS: 16-222 GMDN: 63247	084977100000000000000003M7	

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	<p>Key Surgical Instrument Tip Protectors</p>	<p>PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C</p>			

<p>Tapas para agujas de Kirschner y clavos</p> <p>Fin previsto: Proteger y cubrir agujas de Kirschner y clavos.</p>		<p>H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457</p>			
	<p>Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)</p>	<p>C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS</p>			
<p>Bandeja de esterilización de instrumentos</p> <p>Fin previsto: Protección de los dispositivos en la limpieza, esterilización y almacenamiento.</p>	<p>Key Surgical Plastic Sterilization Trays</p>	<p>PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB</p>	<p>UMDNS:12-143 GMDN: 13730</p>	<p>0849771000000000000004M9</p>	
	<p>Key Surgical Finger Mat</p>	<p>FM-1810</p>			
	<p>Key Surgical Mesh Trays</p>	<p>08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50 DIV116</p>			

		DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Protectores de esquinas para bandejas Fin previsto: proteger las esquinas de la bandeja de esterilización y la envoltura de esterilización	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15-907 GMDN: 63494 & 65133	084977100000000000000005MB	
Limpiador de adhesivo Fin previsto: solución para eliminar los residuos adhesivos de los instrumentos médicos	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN: 64150	084977100000000000000006MD	
Película de aire caliente Fin previsto: indicado para su uso en métodos de esterilización con aire caliente	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735	084977100000000000000007MF	
Envoltorio de esterilización Fin previsto: envoltorio de barrera estéril	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100 CB/TWO120	UMDNS: GMDN: 13735	084977100000000000000008MH	

CB/TWR120
CB/TWRAP060
CB/TWRAP075
CB/TWRAP090
CB/TWRAP100
CB/TWRAP1012
CB/TWRAP120
CB/TWRAP1315
CB/TWRAP1315X
CB/TWRAP150
CB/TWRAP150F3W
CB/TWRAP18135
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CB/TWRAPDRY075
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CB060
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CBU/TWRAP1215
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CBU/TWY120
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CBU1014DB
CBU120
CBU1315
CBU150
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CDB/CG075
CDB/CG075DB
CDB/CG090

CDB/CG100
CDB/CG1012
CDB/CG1012DB
CDB/CG1014
CDB/CG120
CDB/CG120DB
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CDB/CG1315
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CDB/CG140
CDB/CG150
CDB/CG150DB
CDB/CG1815
CDB/CG1815DB
CDB/GC120
CDB/GC140
CDB/TWO090
CDB/TWR120
CDB/TWRAP090
CDB/TWRAP100
CDB140
CDB1815
CDB5075
CDG/CB060
CDG/CB075
CDG/CB075DB
CDG/CB090
CDG/CB100
CDG/CB1012DB
CDG/CB1015
CDG/CB120
CDG/CB120DB
CDG/CB1215DB
CDG/CB1315
CDG/CB1315DB
CDG/CB1815DB
CDG/TWO1215
CDG/TWO1315X
CDG/TWRAP060
CDG/TWRAP075
CDG/TWRAP090
CDG/TWRAP100
CDG/TWRAP100DB
CDG/TWRAP1014
CDG/TWRAP120
CDG/TWRAP120DB
CDG/TWRAP1214
CDG/TWRAP1215
CDG/TWRAP1315
CDG/TWRAP150
CDG/TWY1315
CDG075
CDG090
CDG100
CDG120
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CDG140
CDG150
CDG1815
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CG/CB075DB
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CG/CB1215
CG/CB1215X
CG/CB1315
CG/CB1315/P120
CG/CB1315DB
CG/CB1315X
CG/CB140
CG/CB140X
CG/CB150
CG/CB1715
CG/CB1715/F4
CG/CB1815
CG/CB1815/P72
CG/CB5045
CG/CBA120
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CG/CBU090
CG/CBU100
CG/CBU100DB
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CG/CBU1014
CG/CBU1090
CG/CBU1215
CG/CBU1315DB
CG/CBU1315X
CG/PRO1215
CG/PRO1815
CG/TWO060
CG/TWO090
CG/TWO1012
CG/TWO1012DB
CG/TWO1014
CG/TWO1014DB
CG/TWO1075
CG/TWO1075DB
CG/TWO1090DB
CG/TWO120
CG/TWO1215
CG/TWO1215DB
CG/TWO1215PZDB
CG/TWO1315
CG/TWO140
CG/TWO1715
CG/TWO1715DB
CG/TWO1815
CG/TWO1815DB
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CG/TWR1215PZDB
CG/TWR1315
CG/TWR1315PZDB
CG/TWR1715DB

CG/TWR1815PZDB
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CG/TWRAP075
CG/TWRAP075DB
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CG/TWRAP120DB
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CG/TWRAP1215DB
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CG/TWRAP1315DB
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CG/TWRAP1315PZDB
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CG/TWRAP150
CG/TWRAP1715DB
CG/TWRAP1815
CG/TWRAP1815/F4
CG/TWRAP1815DB
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CG/TWRAP5075DB
CG/TWRAPDRY060DB
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CG/TWRAPDRY090DB
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CG/TWRAPDRY1012
CG/TWRAPDRY1014
CG/TWRAPDRY1075
CG/TWRAPDRY1090
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CG/TWRAPDRY120DB
CG/TWRAPDRY1215
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CG/TWRAPDRY1315X
CG/TWRAPDRY140
CG/TWRAPDRY150
CG/TWRAPDRY1715
CG/TWRAPDRY1815
CG/TWRAPDRY1815M
CG/TWY060
CG/TWY075DB
CG/TWY090
CG/TWY090DB
CG/TWY100
CG/TWY100DB
CG/TWY1012
CG/TWY1012DB
CG/TWY1090
CG/TWY1090DB
CG/TWY1215
CG/TWY1215PZDB

CG/TWY1315
CG/TWY1315DB
CG/TWY1815
CG/WB120
CG/WB1315
CG/WB1815
CG060
CG075
CG075DB
CG090
CG090/P150
CG100
CG100/P150
CG100DB
CG120
CG120DB
CG1215
CG1315
CG140
CG150
CG1715DB
CG1815DB
CG5075
CGP/CB100
CGP/CB120
CGP/CB1715
CGP/CB1815
CGP/CBU100
CGP/CBU1014
CGP/CBU1014DB
CGP/CBU1090
CGP/CBU1215
CGP/CBU1315
CGP/CBU140
CGP/CBU1815
CGP/TWO100
CGP/TWO1012
CGP/TWO1215
CGP/TWO1815
CGP/TWRAP060
CGP/TWRAP060DB
CGP/TWRAP075
CGP/TWRAP075DB
CGP/TWRAP090
CGP/TWRAP100
CGP/TWRAP1012
CGP/TWRAP1075
CGP/TWRAP120
CGP/TWRAP1215
CGP/TWRAP1315
CGP/TWRAP150
CGP/TWRAP1815
CGP/TWY075
CGP/TWY100
CGP/TWY1315
CGP/TWY1815
CGP1315
CGP150
CGX/CB075
CGX/CB075DB
CGX/CB090
CGX/CB100
CGX/CB100DB
CGX/CB1012
CGX/CB1012DB

CGX/CB1014
CGX/CB1090
CGX/CB1090DB
CGX/CB1215
CGX/CB1215DB
CGX/CB1315
CGX/CB1315/P120
CGX/CB1315P120DB
CGX/CB1715
CGX/CB1715DB
CGX/CB1815
CGX/CB1815DB
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CGX/CB5075DB
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CGX/CBU060DB
CGX/CBU100
CGX/CBU1012
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CGX/CBU1014DB
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CGX/CBU1090DB
CGX/CBU1215
CGX/CBU1315
CGX/CBU1315DB
CGX/CBU1815
CGX/TWO1012DB
CGX/TWO1090DB
CGX/TWO1215PZDB
CGX/TWO1315
CGX/TWR1090DB
CGX/TWR1215PZDB
CGX/TWR1715DB
CGX/TWRAP075DB
CGX/TWRAP090
CGX/TWRAP090DB
CGX/TWRAP100
CGX/TWRAP100DB
CGX/TWRAP1012
CGX/TWRAP1012DB
CGX/TWRAP1090DB
CGX/TWRAP1215
CGX/TWRAP1215PZDB
CGX/TWRAP1315
CGX/TWRAP1315PZDB
CGX/TWRAP1715DB
CGX/TWRAP1815
CGX/TWRAP1815DB
CGX/TWRAP5075
CGX/TWRAP5075DB
CGX/TWRAPD100DB
CGX/TWRAPD1215DB
CGX/TWRAPD1315DB
CGX/TWRAPDRY100
CGX/TWRAPDRY1215
CGX/TWRAPDRY1315
CGX/TWY090DB
CGX/TWY1012DB
CGX/TWY1090DB
CGX/TWY1215PZDB
CGX/TWY1315
CGX/TWY1315DB
CGX090
CGX100
CGX100DB

CGX120
 CGX1715DB
 REL340G/CBU100
 REL340G/CBU1014
 REL340G/CBU1215
 REL340G/CBU1315
 RELGRN/CB100
 RELGRN/CB1050
 RELGRN/CB1315
 RELGRN/CB140
 RELGRN/WB1815
 WB/TDRY100DB
 WB/TWO075
 WB/TWO1012
 WB/TWO1014
 WB/TWO1014DB
 WB/TWO1315
 WB/TWRAP060
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 WB/TWRAP090
 WB/TWRAP100
 WB/TWRAP100DB
 WB/TWRAP1012
 WB/TWRAP1014DB
 WB/TWRAP1075
 WB/TWRAP1215
 WB/TWRAP1215DB
 WB/TWRAP1315
 WB/TWRAP1815
 WB/TWRAPDRY060
 WB/TWRAPDRY090
 WB/TWRAPDRY100
 WB/TWRAPDRY120
 WB/TWRAPDRY1315X
 WB/TWRAPDRY150
 WB/TWRAPDRY150F3
 WB/TWY090
 WB/TWY1014
 WB/TWY1215
 WB075
 WB090
 WB100
 WB1014
 WB120
 WB140
 CBA060
 CBU140
 CDG1315
 CG/TWRAPDRY060
 CGX/TWY1215
 WB/TWRAPDRY1012
 MC-CBA/TWRAP090
 MC-CBA/TWRAP100
 MC-CBA/TWRAP120
 RELGRN/CBU100
 RELGRN/CBU140
 CG/CBU120
 CGX/TWY090
 CGX/TWY1012
 CG/CBU1815
 CB/TDRY075
 CB/TDRY090
 CB/TDRY100
 CB/TDRY060
 CB/TDRY120

		CGX/TWR1815			
Envoltorio para transporte Fin previsto: envoltorio de barrera para el transporte	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB TWRAP1014 TWRAP1090DB	GMDN: 13735	0849771000000000000009MK	

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TWRAP1215
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TWRAP1315
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TWRAP140
TWRAP140DB
TWRAP150
TWRAP150DB
TWRAP1715
TWRAP1715DB
TWRAP1815
TWRAP1815DB
TWRAP5090
TWRAP5390
TWRAP7537
TWRAP75375
TWRAPDRY050
TWRAPDRY060
TWRAPDRY075
TWRAPDRY090
TWRAPDRY100
TWRAPDRY1012
TWRAPDRY1014
TWRAPDRY120
TWRAPDRY1315
TWRAPDRY140
TWRAPDRY1815
TWRAPDRY3015
TWRAPDRY3015SGL
TWRAPDRY5075
TWRAPDRY7560
TWRAPDRYOFFCUT
TWY075
TWY075DB
TWY090
TWY100
TWY100DB
TWY1012
TWY1014
TWY120
TWY1215
TWY1215DB
TWY1315
TWY1315DB
TWY140
TWY1715
TWY1715DB
TWY1815
CDBAG002G
H-THCOVER001
H-THCOVER002
H-THCOVER003
H-THOCOVER001
H-THOCOVER002
H-THOCOVER003
H-THRCOVER001
H-THRCOVER002
H-THRCOVER003
H-THYCOVER001
H-THYCOVER002
H-THYCOVER003
PC000700
PC000800
PC000900

		PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Envoltorio para transporte Fin previsto: envoltorio de barrera para el transporte	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN: 13735		
Filtros del recipiente Fin previsto: para usar con recipientes de esterilización.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157 01158	GMDN: 60909	0849771000000000000010M4	

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04111
1070020
26510
27320
27330
27340
27350
27360
55-291-01-04
61140
71140
71141
71194
91140
26515
27325
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27345
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91140
26510
ME01194
ME26515
ME27325
ME27335

		ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Revestimiento para bandejas Fin previsto: para su uso en la esterilización de dispositivos médicos.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007 H-TLC008 H-TLC009 H-TLC010 H-TLC011 H-TLC012 H-TLC013 H-TLC078 H-TLC109 H-TLC110 H-TLC111 H-TLC119 H-TLC213 H-TLC214 H-TLC215 LIB1328 LIB250X320 LIB300X360 LIB300X500 LIB3025 LIB3050 LIB400X500 LINH3020 LINH3041 LINH4555 MILB002 MILB003 MILB004 MILB005 MILB006 MILB007 MILB008 MILB009 MILB011 MILB012 MILB016 MILB017	GMDN: 60908	0849771000000000000011M6	

	MILB019 MILB020 MILB021 MILB022 MILB025 MILB027 MILB029 MILB056 MILB120X250 MILB130X230 MILB170X270 MILB250X300 MILB300X400 MILB305X450 MILB350x450 MILB375X600 MILB450X650 MILB500X900 PC002100 PC002200 PC008800 PC008900 PC009000 PC009100 PC009200 PC009400 PC009800 PC009900 PC010000 PC010200 PC010400 PC010700 PC010800 PC011200 PC011300 PC011400 PC011700 PC011800 PC013300 PC013600 TL-101-200 TL-202-500 TL-203-500 TL-204-500 TLC001 TLC002 TLC004 TLC005 TLC006 TLC007 TLC008 TLC009 TLC010 TLC011 TLC012 TLC013 TLC014 TLC017 TLC018 TLC019 TLC020 TLC022 TLC023 TLC024 TLC027			
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		TLC029R TLC030 TLC031 TLC034 TLC036 TLC045 TLC051 TLC052 TLC055 TLC060 TLC066 TLC069 TLC071 TLC072 TLC078 TLC079 TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300 PC013100 PC013200	GMDN: 61664		

		SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Aceite de mantenimiento Fin previsto: indicado para lubricar dispositivos médicos.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	0849771000000000000012M8	
Chiol Ultra Fin previsto: solución de limpieza para eliminar la suciedad de las de superficies metálicas.	Chiol Ultra	02110	GMDN: 63385	0849771000000000000013MA	

Por la presente,
nombramos a

Medical Device Safety Service (MDSS)
Schiffgraben 41
D-30175 Hannover
Alemania

como el representante autorizado europeo, según se define en el artículo 2(32) de MDR.

Ruta de evaluación de conformidad: Anexo IV

Emitido por:

Firma:



Fecha: 2021-12-28

Nombre:

Coletta Cohara

Cargo:

Director de Calidad y Cumplimiento normativo

Lugar de

Key Surgical LLC

emisión del

8101 Wallace Rd.

documento:

Eden Prairie, MN 55344

USA

Me, valmistaja,

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

vakuutamme yksin omalla vastuullamme, että seuraavat luokan I epästeriilit (MDR:n mukaisesti), ei-uudelleenkäytettävät, ei-mittaavat lääkinälliset laitteet täyttävät EU:n lääkinällisiä laitteita koskevan asetuksen 2017/745 (MDR) liitteen IV niitä koskevat vaatimukset. Nämä laitteet ovat EU:n vaatimustenmukaisuusvakuutuksen julkaisusta säättävän, lääkinällisiä laitteita koskevan asetuksen 2017/745 mukaisia. Kaikkea tätä tukevaa dokumentaatiota säilytetään valmistajan tiloissa.

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
Puhdistusharjat	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	084977100000000000000001M3	Euroopan komissio ei ole säättänyt MDR:n mukaisesti mistään yleisistä teknisistä tiedoista, jotka koskisivat tässä vakuutuksessa mainittua Key Surgical -tuotetta. Sovellettavat tunnistetut standardit mainitaan teknisessä dokumentaatio ssa.
	Käyttötarkoitus: lääkinällisten laitteiden puhdistaminen	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336 09338 09339 09340		

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		09341			
		09342			
		09343			
		09344			
		09345			
		09346			
		09365			
		09366			
		09380			
		09388			
		09499			
		09745			
		09746			
		09747			
		AT-12-062			
		AT-12-062-50			
		AT-12-087			
		AT-12-087-50			
		AT-12-105			
		AT-12-105-50			
		AT-12-118			
		AT-12-118-50			
		AT-12-125			
		AT-12-125-50			
		AT-12-131			
		AT-12-131-50			
		AT-12-158			
		AT-12-158-50			
		AT-12-197			
		AT-12-197-50			
		AT-12-250			
		AT-12-250-50			
		AT-12-276			
		AT-12-276-50			
		AT-12-375			
		AT-12-375-50			
		AT-12-440			
		AT-12-440-50			
		AT-18-062			
		AT-18-062-50			
		AT-18-087			
		AT-18-087-50			
		AT-18-105			
		AT-18-105-50			
		AT-18-118			
		AT-18-118-50			
		AT-18-125			
		AT-18-125-50			
		AT-18-131			
		AT-18-131-50			
		AT-18-158			
		AT-18-158-50			
		AT-18-197			
		AT-18-197-50			
		AT-18-250			
		AT-18-250-50			
		AT-18-276			
		AT-18-276-50			
		AT-18-375			
		AT-18-375-50			
		AT-18-440			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		AT-18-440-50			
		AT-24-062			
		AT-24-062-50			
		AT-24-087			
		AT-24-087-50			
		AT-24-105			
		AT-24-105-50			
		AT-24-118			
		AT-24-118-50			
		AT-24-125			
		AT-24-125-50			
		AT-24-131			
		AT-24-131-50			
		AT-24-158			
		AT-24-158-50			
		AT-24-197			
		AT-24-197-50			
		AT-24-250			
		AT-24-250-50			
		AT-24-276			
		AT-24-276-50			
		AT-24-375			
		AT-24-375-50			
		AT-24-440			
		AT-24-440-50			
		B-2100-50			
		BBR001			
		BBR002			
		BBR003			
		BR-04-003			
		BR-04-003-50			
		BR-04-080			
		BR-04-080-50			
		BR-06-039-50			
		BR-06-062			
		BR-06-062-50			
		BR-06-079			
		BR-06-079-50			
		BR-06-250			
		BR-06-250-50			
		BR-06-375			
		BR-06-375-50			
		BR-06-500			
		BR-06-500-50			
		BR-07-075			
		BR-07-075-50			
		BR-07-107			
		BR-07-107-50			
		BR-08-039			
		BR-08-039-50			
		BR-08-070			
		BR-08-070-50			
		BR-08-079			
		BR-08-079-50			
		BR-08-087			
		BR-08-087-50			
		BR-08-092			
		BR-08-092-50			
		BR-08-105			
		BR-08-105-50			
		BR-08-118			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		BR-08-118-50			
		BR-08-131			
		BR-08-131-50			
		BR-08-144			
		BR-08-144-50			
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		BR-08-158-50			
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		BR-08-440			
		BR-08-440-50			
		BR-08-630			
		BR-08-630-50			
		BR-12-079			
		BR-12-079-50			
		BR-12-118			
		BR-12-118-50			
		BR-12-158			
		BR-12-158-50			
		BR-12-197			
		BR-12-197-50			
		BR-12-236			
		BR-12-236-50			
		BR-16-197			
		BR-16-197-50			
		BR-16-236			
		BR-16-236-50			
		BR-16-276			
		BR-16-276-50			
		BR-16-393			
		BR-16-393-50			
		BR-16-443			
		BR-16-443-50			
		BR-16-472			
		BR-16-472-50			
		BR-16-591			
		BR-16-591-50			
		BR-16-787			
		BR-16-787-50			
		BR-18-039			
		BR-18-039-50			
		BR-18-062			
		BR-18-062-50			
		BR-18-070			
		BR-18-070-50			
		BR-18-087			
		BR-18-087-50			
		BR-18-105			
		BR-18-105-50			
		BR-18-125			
		BR-18-125-50			
		BR-18-158			
		BR-18-158-50			
		BR-18-197			
		BR-18-197-50			
		BR-18-250			
		BR-18-250-50			
		BR-18-393			
		BR-18-393-50			
		BR-18-591-50			
		BR-18-880-50			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		BR-2300			
		BR-24-070-50			
		BR-24-080-50			
		BR-24-098-50			
		BR-24-197-50			
		BR-24-200-50			
		BR-24-236-50			
		BR-24-276-50			
		BR-24-312-50			
		BR-24-375-50			
		BR-24-393-50			
		BR-24-425-50			
		BR-24-440-50			
		BR-24-443-50			
		BR-24-880-50			
		BR-4199			
		BR-4299			
		BR-4399			
		BR-4499			
		BR-4599			
		BR-4699			
		BR-4799			
		BR-4899			
		BR-4999			
		BR-5099			
		BR-5199C			
		BR-6099			
		BR-8110			
		BR-8110-50			
		BR-8115			
		BR-8115-50			
		BR-8210			
		BR-8210-50			
		BR-8310			
		BR-8310-50			
		BR-8315			
		BR-8315-50			
		BR-8410			
		BR-8410-50			
		BZ-06-2550			
		BZ-06-2550-50			
		BZ-08-125			
		BZ-08-125-50			
		BZ-10-050			
		BZ-10-050-50			
		BZ-12-062			
		BZ-12-062-50			
		BZ-12-087			
		BZ-12-087-50			
		BZ-12-098			
		BZ-12-098-50			
		BZ-12-125			
		BZ-12-125-50			
		BZ-12-158			
		BZ-12-158-50			
		BZ-16-250			
		BZ-16-250-50			
		BZ-18-062			
		BZ-18-062-50			
		BZ-18-079			
		BZ-18-079-50			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		BZ-18-1000			
		BZ-18-1000-50			
		BZ-18-105			
		BZ-18-105-50			
		BZ-18-125			
		BZ-18-125-50			
		BZ-18-131			
		BZ-18-131-50			
		BZ-18-144			
		BZ-18-144-50			
		BZ-18-1543			
		BZ-18-1543-50			
		BZ-18-158			
		BZ-18-158-50			
		BZ-18-197			
		BZ-18-197-50			
		BZ-18-236			
		BZ-18-236-50			
		BZ-18-250			
		BZ-18-250-50			
		BZ-18-312			
		BZ-18-312-50			
		BZ-18-354			
		BZ-18-354-50			
		BZ-18-393			
		BZ-18-393-50			
		BZ-18-433			
		BZ-18-433-50			
		BZ-18-472			
		BZ-18-472-50			
		BZ-24-125			
		BZ-24-125-50			
		FLEX001			
		FLEX002			
		FLEX003			
		FLEX004			
		FLEX005			
		FLEX006			
		FLEX007			
		FLEX007A			
		FLEX007B			
		FLEX011			
		FLEX021			
		FLEX022			
		FLEX023			
		FLEX024			
		FLEX028			
		FLEX033			
		FLEXSAMP			
		FT-12-197			
		FT-12-197-50			
		FT-12-250			
		FT-12-250-50			
		FT-12-276			
		FT-12-276-50			
		FT-12-375			
		FT-12-375-50			
		FT-12-440			
		FT-12-440-50			
		FT-12-500			
		FT-12-500-50			

Tuoteperhe	Tuotteen kaupan nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		FT-18-197			
		FT-18-197-50			
		FT-18-250			
		FT-18-250-50			
		FT-18-276			
		FT-18-276-50			
		FT-18-375			
		FT-18-375-50			
		FT-18-440			
		FT-18-440-50			
		FT-18-500			
		FT-18-500-50			
		FT-24-197			
		FT-24-197-50			
		FT-24-250			
		FT-24-250-50			
		FT-24-276			
		FT-24-276-50			
		FT-24-375			
		FT-24-375-50			
		FT-24-440			
		FT-24-440-50			
		FT-24-500			
		FT-24-500-50			
		H-FLEX001			
		H-FLEX002			
		H-FLEX003			
		H-FLEX004			
		H-FLEX005			
		H-FLEX006			
		H-FLEX007			
		H-FLEX007A			
		H-FLEX008H			
		H-FLEX009			
		H-FLEX010			
		H-FLEX021			
		H-FLEX022			
		H-FLEX023			
		H-FLEX024			
		H-FLEX025			
		H-FLEX026			
		H-FLEX027			
		H-FLEX033			
		H-FLEX034			
		H-FLEX035			
		H-FLEXSAMP			
		MED100.10			
		MED100.11			
		MED100.12			
		MED100.13			
		MED100.14			
		MED100.15			
		MED100.16			
		MED100.17			
		MED100.18			
		MED100.19			
		MED100.20			
		MED100.21			
		MED100.22			
		MED100.23			
		MED100.24			

Tuoteperhe	Tuotteen kaupan nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		MED100.25			
		MED100.26			
		MED100.27			
		MED100.28			
		MED100.29			
		MED100.30			
		MED100.31			
		MED100.32			
		MED100.48			
		MED100.49			
		MED100.52			
		MED100.57			
		MED100.58			
		MED100.59			
		MED100.61			
		MED100.62			
		MJ-370			
		MJ-370C-1			
		PC-100C			
		PC-112C			
		PC-200C			
		PC-212C			
		PC-300P			
		PC-306P			
		PC-312P			
		PC-400P			
		PC-412P			
		PC-503			
		PC-512			
		PC-515			
		PP-16-039			
		PP-16-039-50			
		PP-16-062			
		PP-16-062-50			
		PP-16-087			
		PP-16-087-50			
		PP-16-105			
		PP-16-105-50			
		PP-16-125			
		PP-16-125-50			
		PP-16-158			
		PP-16-158-50			
		PP-18-197			
		PP-18-197-50			
		PP-18-250			
		PP-18-250-50			
		PP-18-393			
		PP-18-393-50			
		PP-18-591			
		PP-18-591-50			
		PP-18-750			
		PP-18-750-50			
		PP-22-039-50			
		PP-22-062-50			
		PP-22-087-50			
		PP-22-105-50			
		PP-22-125-50			
		PP-22-158-50			
		PP-22-197-50			
		PP-24-250-50			
		PT-28-118-50			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		PT-28-197-50 BR-06-039 PP-22-039 PP-22-062 PP-22-087 PP-22-105 PP-22-125 PP-22-158 PP-22-197 PP-24-250 PT-28-118 PT-28-197 FLEX008 FLEX009 FLEX025 FLEX026 BR-18-591 BR-18-880 BR-24-070 BR-24-080 BR-24-098 BR-24-197 BR-24-200 BR-24-236 BR-24-276 BR-24-312 BR-24-375 BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4 96281.7 MED100.98 26474			

Tuoteperhe	Tuotteen kaupan nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197 BR-31-276 BR-3201 BR-3201-50 BR-4140			
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600			
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50			

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325			
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50 BR-075-24 BR-075-24-50 BR-075-32 BR-075-32-50 BR-075-42 BR-075-42-50 BR-075-99 BR-100-18 BR-100-18-50 BR-100-24 BR-100-24-50 BR-100-32 BR-100-32-50 BR-100-42 BR-100-42-50 BR-100-99, BR-150-18 BR-150-18-50 BR-150-24 BR-150-24-50 BR-150-32 BR-150-32-50 BR-150-42 BR-150-42-50 BR-150-99 BR-200-18 BR-200-18-50 BR-200-24			

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		BR-200-24-50 BR-200-32 BR-200-32-50 BR-200-42 BR-200-42-50 BR-200-99 BR-3030 BR-3030-50 BR-3035 BR-3035-50 BR-3040 BR-3040-50 BR-3202 BR-3202-50 BR-3299 BR-3300 BR-3305 BR-3307 BR-3308 BR-3308-50 BR-3309 BR-3309-50 BR-3310 BR-3310-50 BR-3320 BR-3320-50 BR-3330 BR-3330-50 BR-3340 BR-3340-50 BR-3399 BR-3410 BR-3410-50 BR-3420 BR-3420-50 BR-3701 BR-3702 BR-3703 BR-3711-100 BR-3711-50 BR-3799-50 BR-3711			
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21-134 GMDN: 38835		
Huuhtelukanyylit Käyttötarkoitus: tarkoitettu käytettäväksi haavan huuhtelussa.	Key Surgical Cannulas (non-sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15-206 GMDN: 62389	08497710000000000000002M5	
	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06-01, 01800, 3-06-02, 13-06-02, 01801, 3-06-03, 13-06-03, 01802, 3-06-04, 13-06-04, 01803, 3-06-05, 13-06-05, 01804, 3-06-07, 13-06-07,	UMDNS: 16-222		

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
Instrumenttisuojat	Käyttötarkoitus: tarkoitettu lääkinnällisten instrumenttien peittämiseen ja suojaamiseen.	01805, 3-11-01, I3-11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11-03, 01828, 3-11-04, I3-11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12-01, 01838, 3-12-02, I3-12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, I3-12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12-09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10-04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09-03, 01814, 3-09-04, I3-09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09-08, I3-09-08, 01472, 01473, 3-09-09, 01474, 01475, 01494, 3-09-10, 3-24-98, 3-24-99, 3-48-50, 3-80-03, 3-60-01, 3-60-02, 3-60-03, 3-60-04, 3-60-05, 3-60-06, 3-60-07, 3-60-08, 3-60-09, 3-60-10, 3-60-11, 01471, 01476, 01477, 01469, 01470, 01478, 01479, 01492, 01496, 01499, 3-01-01, 01865, 3-01-02, 01890, 3-01-03, 01866, 3-01-04, 01867, 3-01-05, 01891, 3-01-06, 01892, 3-02-01, 01876, 3-02-02, 3-02-03, 01877, 3-02-04, 01878, 3-02-06, 3-03-01, 01871, 3-03-02, 01872, 3-03-03, 01873, 3-03-04, 01874, 3-03-05, 01875, 3-03-06, 3-04-01, 01484, 3-04-02,	GMDN: 63247	084977100000000000000003M7	

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		01485, 3-04-03, 01486, 3-04-04, 01487, 3-04-05, 01488, 3-04-06, 01489, 3-08-01, 01460, 3-08-02, 01461, 3-08-03, 01462, 3-08-04, 01463, 3-08-05, 01464, 3-08-06, 01465, 3-09-01, 3-09-02S, 3-15-01, 01868, 3-15-02, 01869, 3-15-03, 01870, 3-15-04, 01884, 3-15-05, 01885, 3-15-06, 01886, 3-21-03, 3-24-06, 3-24-20, , 3-42-95, 3-44-01, 3-44-02, 3-44-03, 3-44-04, 3-44-05, 3-44-06, 3-44-96, 3-44-97, 3-48-01,, 3-48-02, 3-48-03, 3-48-04, 3-48-05, 3-48-06, ,3-48-61, 3-48-62, 3-48-94, 3-48-95, 3-74-05, 3-74-06, I3-03-01, I3-03-02, I3-03-03, I3-04-01, I3-04-02, I3-04-03, I3-04-04, I3-04-05, I3-04-06, I3-08-01, I3-08-02, I3-08-03, I3-08-04, I3-08-05, I3-08-06,3-03-11, 3-03-12, 3-03-13, 3-03-15, 3-04-11, 01806, 3-04-12, 01807, 3-04-13, 01808, 01809, 3-04-17, 01811, 3-04-18, 01812, 3-04-19, 01813, 3-08-11, 3-08-12, 3-08-13, 3-08-15, 3-08-17, 3-08-18, 3-08-19, 3-24-11, 3-24-13, 3-24-15, 3-24-17, 3-44-11, 3-44-12, 3-44-13, 3-44-15, 3-44-16, 3-44-17, 3-44-18, 3-44-19, 3-48-11, 3-48-12, 3-48-13, 3-48-15, 3-48-16,3-48-17, 3-48-18, 3-48-19, 3-74-11, 3-74-15, 3-78-11, I3-04-11, I3-04-12, I3-04-13, I3-04-15, I3-04-18, 3-04-07, 01480, 3-04-08, 01481, 3-04-09, 01482, 01810, 3-08-07, 01466, 3-08-08, 01467, 3-08-09, 01468, 3-15-07, 01887, 3-15-08, 01888, 3-15-09, 01889, 3-24-08, 3-24-09, 3-44-07, 3-44-08, 3-44-09, 3-48-07, 3-48-08, 3-48-09, 3-74-07, 3-74-09, I3-04-07, I3-04-08, I3-04-09, I3-08-07, I3-08-08, I3-			

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
K-johto- ja neulasuojukset Käyttötarkoitus: suojaa ja peitä K-johdot ja		08-09, 3-01-07, 3-01-08, 01824, 3-01-09, 3-02-07, 01879, 3-02-08, 3-02-09, 3-03-07, 3-03-08, 3-03-09, 3-16-05, 3-16-06, 3-16-07, 3-16-08, 01821, 3-16-09, 30000, 30001, 30002, 30003, 30004, 30005, 30006, 30007,30008, 30009, 30010, 30012, 30013, 30014, 30015, 30016, 30017, 01850, 01851, 01852, 01853, 01854, TP-09-11, TP-09-12, TP-09-13, 3-02-05, 3-04-15 3-06-50 3-08-09 3-08-100 3-11-01 01826			
	Key Surgical Instrument Tip Protectors	PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457			
	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS			

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
neulat.					
Instrumenttien sterilointitarjottimet Käyttötarkoitus: laitteiden suojaaminen puhdistuksen, steriloinnin ja säilytyksen aikana.	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS:12-143 GMDN: 13730	084977100000000000000004M9	
	Key Surgical Finger Mat	FM-1810			
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50 DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940			

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Tarjottimen kulmien suojuukset Käyttötarkoitus: sterilointitarjottimen kulmien ja sterilointikäären suojaaminen.	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15-907 GMDN: 63494 & 65133	084977100000000000000005MB	
Liimanpoistoaine Käyttötarkoitus: liuos liimajäämien poistamiseen lääkkinnällisistä instrumenteista	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN:64150	084977100000000000000006MD	
Kuumailmakalvo Käyttötarkoitus: tarkoitettu käytettäväksi kuumailmasterilointimenetelmissä	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735	084977100000000000000007MF	
Sterilointikääre Käyttötarkoitus: steriili kalvokääre	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100 CB/TWO120 CB/TWR120 CB/TWRAP060 CB/TWRAP075 CB/TWRAP090 CB/TWRAP100 CB/TWRAP1012	UMDNS: GMDN: 13735	084977100000000000000008MH	

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		CB/TWRAP120 CB/TWRAP1315 CB/TWRAP1315X CB/TWRAP150 CB/TWRAP150F3W CB/TWRAP18135 CB/TWRAP1815 CB/TWRAP5075 CB/TWRAPDRY050 CB/TWRAPDRY060 CB/TWRAPDRY075 CB/TWRAPDRY090 CB/TWRAPDRY100 CB/TWRAPDRY120 CB/TWRAPDRY1315X CB/TWRAPDRY140 CB/TWY100 CB/TWY120 CB030 CB050 CB060 CB075 CB090 CB100 CB100DB CB1012 CB1014 CB120 CB120DB CB1315 CB1315DB CB140 CB150 CB1540 CB1715 CB1715DB CB1815 CB1815DB CBA/TWRAP120 CBA/TWRAP140 CBA050 CBA075 CBA090 CBA100 CBA120 CBA1415 CBU/TWRAP100 CBU/TWRAP1215 CBU/TWRAP1315 CBU/TWY120 CBU1014 CBU1014DB CBU120 CBU1315 CBU150 CDB/CG060 CDB/CG075 CDB/CG075DB CDB/CG090 CDB/CG100 CDB/CG1012			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		CDB/CG1012DB CDB/CG1014 CDB/CG120 CDB/CG120DB CDB/CG1215 CDB/CG1215DB CDB/CG1315 CDB/CG1315DB CDB/CG140 CDB/CG150 CDB/CG150DB CDB/CG1815 CDB/CG1815DB CDB/GC120 CDB/GC140 CDB/TWO090 CDB/TWR120 CDB/TWRAP090 CDB/TWRAP100 CDB140 CDB1815 CDB5075 CDG/CB060 CDG/CB075 CDG/CB075DB CDG/CB090 CDG/CB100 CDG/CB1012DB CDG/CB1015 CDG/CB120 CDG/CB120DB CDG/CB1215DB CDG/CB1315 CDG/CB1315DB CDG/CB1815DB CDG/TWO1215 CDG/TWO1315X CDG/TWRAP060 CDG/TWRAP075 CDG/TWRAP090 CDG/TWRAP100 CDG/TWRAP100DB CDG/TWRAP1014 CDG/TWRAP120 CDG/TWRAP120DB CDG/TWRAP1214 CDG/TWRAP1215 CDG/TWRAP1315 CDG/TWRAP150 CDG/TWY1315 CDG075 CDG090 CDG100 CDG120 CDG1215 CDG140 CDG150 CDG1815 CG/CB050 CG/CB060 CG/CB075			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		CG/CB075DB			
		CG/CB090			
		CG/CB100			
		CG/CB100DB			
		CG/CB1012			
		CG/CB1014			
		CG/CB1014DB			
		CG/CB1075			
		CG/CB1075DB			
		CG/CB1090			
		CG/CB120			
		CG/CB1215			
		CG/CB1215X			
		CG/CB1315			
		CG/CB1315/P120			
		CG/CB1315DB			
		CG/CB1315X			
		CG/CB140			
		CG/CB140X			
		CG/CB150			
		CG/CB1715			
		CG/CB1715/F4			
		CG/CB1815			
		CG/CB1815/P72			
		CG/CB5045			
		CG/CBA120			
		CG/CBU075			
		CG/CBU090			
		CG/CBU100			
		CG/CBU100DB			
		CG/CBU1012			
		CG/CBU1014			
		CG/CBU1090			
		CG/CBU1215			
		CG/CBU1315DB			
		CG/CBU1315X			
		CG/PRO1215			
		CG/PRO1815			
		CG/TWO060			
		CG/TWO090			
		CG/TWO1012			
		CG/TWO1012DB			
		CG/TWO1014			
		CG/TWO1014DB			
		CG/TWO1075			
		CG/TWO1075DB			
		CG/TWO1090DB			
		CG/TWO120			
		CG/TWO1215			
		CG/TWO1215DB			
		CG/TWO1215PZDB			
		CG/TWO1315			
		CG/TWO140			
		CG/TWO1715			
		CG/TWO1715DB			
		CG/TWO1815			
		CG/TWO1815DB			
		CG/TWR060			
		CG/TWR090DB			
		CG/TWR100			
		CG/TWR100DB			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		CG/TWR1014 CG/TWR1090DB CG/TWR1215PZDB CG/TWR1315 CG/TWR1315PZDB CG/TWR1715DB CG/TWR1815PZDB CG/TWRAP060 CG/TWRAP075 CG/TWRAP075DB CG/TWRAP090 CG/TWRAP090DB CG/TWRAP100 CG/TWRAP100DB CG/TWRAP1012 CG/TWRAP1012DB CG/TWRAP1014 CG/TWRAP1014DB CG/TWRAP1075 CG/TWRAP1090 CG/TWRAP1090DB CG/TWRAP120 CG/TWRAP120DB CG/TWRAP1215 CG/TWRAP1215DB CG/TWRAP1215PZDB CG/TWRAP1315 CG/TWRAP1315DB CG/TWRAP1315PZ CG/TWRAP1315PZDB CG/TWRAP140 CG/TWRAP140DB CG/TWRAP150 CG/TWRAP1715DB CG/TWRAP1815 CG/TWRAP1815/F4 CG/TWRAP1815DB CG/TWRAP5075 CG/TWRAP5075DB CG/TWRAPDRY060DB CG/TWRAPDRY075 CG/TWRAPDRY090 CG/TWRAPDRY090DB CG/TWRAPDRY100 CG/TWRAPDRY1012 CG/TWRAPDRY1014 CG/TWRAPDRY1075 CG/TWRAPDRY1090 CG/TWRAPDRY120 CG/TWRAPDRY120DB CG/TWRAPDRY1215 CG/TWRAPDRY1315 CG/TWRAPDRY1315D CG/TWRAPDRY1315X CG/TWRAPDRY140 CG/TWRAPDRY150 CG/TWRAPDRY1715 CG/TWRAPDRY1815 CG/TWRAPDRY1815M CG/TWY060 CG/TWY075DB			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		CG/TWY090 CG/TWY090DB CG/TWY100 CG/TWY100DB CG/TWY1012 CG/TWY1012DB CG/TWY1090 CG/TWY1090DB CG/TWY1215 CG/TWY1215PZDB CG/TWY1315 CG/TWY1315DB CG/TWY1815 CG/WB120 CG/WB1315 CG/WB1815 CG060 CG075 CG075DB CG090 CG090/P150 CG100 CG100/P150 CG100DB CG120 CG120DB CG1215 CG1315 CG140 CG150 CG1715DB CG1815DB CG5075 CGP/CB100 CGP/CB120 CGP/CB1715 CGP/CB1815 CGP/CBU100 CGP/CBU1014 CGP/CBU1014DB CGP/CBU1090 CGP/CBU1215 CGP/CBU1315 CGP/CBU140 CGP/CBU1815 CGP/TWO100 CGP/TWO1012 CGP/TWO1215 CGP/TWO1815 CGP/TWRAP060 CGP/TWRAP060DB CGP/TWRAP075 CGP/TWRAP075DB CGP/TWRAP090 CGP/TWRAP100 CGP/TWRAP1012 CGP/TWRAP1075 CGP/TWRAP120 CGP/TWRAP1215 CGP/TWRAP1315 CGP/TWRAP150			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		CGP/TWRAP1815 CGP/TWY075 CGP/TWY100 CGP/TWY1315 CGP/TWY1815 CGP1315 CGP150 CGX/CB075 CGX/CB075DB CGX/CB090 CGX/CB100 CGX/CB100DB CGX/CB1012 CGX/CB1012DB CGX/CB1014 CGX/CB1090 CGX/CB1090DB CGX/CB1215 CGX/CB1215DB CGX/CB1315 CGX/CB1315/P120 CGX/CB1315P120DB CGX/CB1715 CGX/CB1715DB CGX/CB1815 CGX/CB1815DB CGX/CB5075 CGX/CB5075DB CGX/CBU060 CGX/CBU060DB CGX/CBU100 CGX/CBU1012 CGX/CBU1014 CGX/CBU1014DB CGX/CBU1090 CGX/CBU1090DB CGX/CBU1215 CGX/CBU1315 CGX/CBU1315DB CGX/CBU1815 CGX/TWO1012DB CGX/TWO1090DB CGX/TWO1215PZDB CGX/TWO1315 CGX/TWR1090DB CGX/TWR1215PZDB CGX/TWR1715DB CGX/TWRAP075DB CGX/TWRAP090 CGX/TWRAP090DB CGX/TWRAP100 CGX/TWRAP100DB CGX/TWRAP1012 CGX/TWRAP1012DB CGX/TWRAP1090DB CGX/TWRAP1215 CGX/TWRAP1215PZDB CGX/TWRAP1315 CGX/TWRAP1315PZDB CGX/TWRAP1715DB CGX/TWRAP1815			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		CGX/TWRAP1815DB CGX/TWRAP5075 CGX/TWRAP5075DB CGX/TWRAPD100DB CGX/TWRAPD1215DB CGX/TWRAPD1315DB CGX/TWRAPDRY100 CGX/TWRAPDRY1215 CGX/TWRAPDRY1315 CGX/TWY090DB CGX/TWY1012DB CGX/TWY1090DB CGX/TWY1215PZDB CGX/TWY1315 CGX/TWY1315DB CGX090 CGX100 CGX100DB CGX120 CGX1715DB REL340G/CBU100 REL340G/CBU1014 REL340G/CBU1215 REL340G/CBU1315 RELGRN/CB100 RELGRN/CB1050 RELGRN/CB1315 RELGRN/CB140 RELGRN/WB1815 WB/TDRY100DB WB/TWO075 WB/TWO1012 WB/TWO1014 WB/TWO1014DB WB/TWO1315 WB/TWRAP060 WB/TWRAP075 WB/TWRAP090 WB/TWRAP100 WB/TWRAP100DB WB/TWRAP1012 WB/TWRAP1014DB WB/TWRAP1075 WB/TWRAP1215 WB/TWRAP1215DB WB/TWRAP1315 WB/TWRAP1815 WB/TWRAPDRY060 WB/TWRAPDRY090 WB/TWRAPDRY100 WB/TWRAPDRY120 WB/TWRAPDRY1315X WB/TWRAPDRY150 WB/TWRAPDRY150F3 WB/TWY090 WB/TWY1014 WB/TWY1215 WB075 WB090 WB100 WB1014			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		WB120 WB140 CBA060 CBU140 CDG1315 CG/TWRAPDRY060 CGX/TWY1215 WB/TWRAPDRY1012 MC-CBA/TWRAP090 MC-CBA/TWRAP100 MC-CBA/TWRAP120 RELGRN/CBU100 RELGRN/CBU140 CG/CBU120 CGX/TWY090 CGX/TWY1012 CG/CBU1815 CB/TDRY075 CB/TDRY090 CB/TDRY100 CB/TDRY060 CB/TDRY120 CGX/TWR1815			
Kuljetuskääre Käyttötarkoitus: kalvokääre kuljetukseen	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB	GMDN: 13735	0849771000000000000009MK	

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB TWRAP1014 TWRAP1090DB TWRAP120 TWRAP1215 TWRAP1215DB TWRAP1315 TWRAP1315DB TWRAP140 TWRAP140DB TWRAP150 TWRAP150DB TWRAP1715 TWRAP1715DB TWRAP1815 TWRAP1815DB TWRAP5090 TWRAP5390 TWRAP7537 TWRAP75375 TWRAPDRY050 TWRAPDRY060 TWRAPDRY075 TWRAPDRY090 TWRAPDRY100 TWRAPDRY1012 TWRAPDRY1014 TWRAPDRY120 TWRAPDRY1315 TWRAPDRY140 TWRAPDRY1815 TWRAPDRY3015 TWRAPDRY3015SGL TWRAPDRY5075 TWRAPDRY7560 TWRAPDRYOFFCUT TWY075 TWY075DB TWY090			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		TWY100 TWY100DB TWY1012 TWY1014 TWY120 TWY1215 TWY1215DB TWY1315 TWY1315DB TWY140 TWY1715 TWY1715DB TWY1815 CDBAG002G H-THCOVER001 H-THCOVER002 H-THCOVER003 H-THCOVER001 H-THCOVER002 H-THCOVER003 H-THRCOVER001 H-THRCOVER002 H-THRCOVER003 H-THRCOVER001 H-THRCOVER002 H-THRCOVER003 H-THYCOVER001 H-THYCOVER002 H-THYCOVER003 PC000700 PC000800 PC000900 PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Kuljetuskääre Käyttötarkoitus: kalvokääre kuljetukseen	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002	GMDN: 13735		

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400			
Säiliösuodattimet Käyttötarkoitus: käytettäväksi sterilointisäiliöiden kanssa.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157 01158 01167 01168 01181 01183 01186 01188 01189 01194 01196 01198 01300 01304 01306 01312 01314 01315 01317 01318 01319 01321 01322 01323 01327 01330 01331 01332 01346 01347	GMDN: 60909	0849771000000000000010M4	

Tuoteperhe	Tuotteen kaupan nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		01348 01350 01355 01356 01363 01365 01366 01367 01368 01369 01373 04111 1070020 26510 27320 27330 27340 27350 27360 55-291-01-04 61140 71140 71141 71194 91140 26515 27325 27335 27345 27355 27365 91140 26510 ME01194 ME26515 ME27325 ME27335 ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Tarjotinvuorit	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002	GMDN: 60908	0849771000000000000011M6	
		Käyttötarkoitus: käytettäväksi lääkinnällisten laitteiden steriloinnissa.			

Tuoteperhe	Tuotteen kaupan nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		H-CBL003			
		H-TLC004			
		H-TLC005			
		H-TLC006			
		H-TLC007			
		H-TLC008			
		H-TLC009			
		H-TLC010			
		H-TLC011			
		H-TLC012			
		H-TLC013			
		H-TLC078			
		H-TLC109			
		H-TLC110			
		H-TLC111			
		H-TLC119			
		H-TLC213			
		H-TLC214			
		H-TLC215			
		LIB1328			
		LIB250X320			
		LIB300X360			
		LIB300X500			
		LIB3025			
		LIB3050			
		LIB400X500			
		LINH3020			
		LINH3041			
		LINH4555			
		MILB002			
		MILB003			
		MILB004			
		MILB005			
		MILB006			
		MILB007			
		MILB008			
		MILB009			
		MILB011			
		MILB012			
		MILB016			
		MILB017			
		MILB019			
		MILB020			
		MILB021			
		MILB022			
		MILB025			
		MILB027			
		MILB029			
		MILB056			
		MILB120X250			
		MILB130X230			
		MILB170X270			
		MILB250X300			
		MILB300X400			
		MILB305X450			
		MILB350x450			
		MILB375X600			
		MILB450X650			
		MILB500X900			
		PC002100			
		PC002200			

Tuoteperhe	Tuotteen kaupp nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		PC008800			
		PC008900			
		PC009000			
		PC009100			
		PC009200			
		PC009400			
		PC009800			
		PC009900			
		PC010000			
		PC010200			
		PC010400			
		PC010700			
		PC010800			
		PC011200			
		PC011300			
		PC011400			
		PC011700			
		PC011800			
		PC013300			
		PC013600			
		TL-101-200			
		TL-202-500			
		TL-203-500			
		TL-204-500			
		TLC001			
		TLC002			
		TLC004			
		TLC005			
		TLC006			
		TLC007			
		TLC008			
		TLC009			
		TLC010			
		TLC011			
		TLC012			
		TLC013			
		TLC014			
		TLC017			
		TLC018			
		TLC019			
		TLC020			
		TLC022			
		TLC023			
		TLC024			
		TLC027			
		TLC029R			
		TLC030			
		TLC031			
		TLC034			
		TLC036			
		TLC045			
		TLC051			
		TLC052			
		TLC055			
		TLC060			
		TLC066			
		TLC069			
		TLC071			
		TLC072			
		TLC078			
		TLC079			

Tuoteperhe	Tuotteen kauppanimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300 PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS	GMDN:61664		

Tuoteperhe	Tuotteen kaupan nimi	Item Number	Tuotekoodi(t)	Perus-UDI-DI	Yleiset tekniset tiedot
		SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Kunnossapitoöljy	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	084977100000000000000012M8	
Käyttötarkoitus: tarkoitettu lääkinnällisten laitteiden voiteluun.					
Chirol Ultra	Chirol Ultra	02110	GMDN: 63385	084977100000000000000013MA	
Käyttötarkoitus: puhdistusliuos lian poistamiseen metallipinnoilta					

Täten nimeämme Medical Device Safety Service (MDSS) -yhtiön
Schiffgraben 41
D-30175 Hannover
Germany

valtuutetuksi edustajaksi Euroopassa MDR:n artiklan 2(32) mukaisesti.

Vaatimustenmukaisuuden arviointireitti: liite IV

Julkaisija:

Allekirjoitus:



Päiväys:

2021-12-28

Nimi: Coletta Cohara
Asema: Laadunvalvonta- ja säännöstenmukaisuusjohtaja
**Vaatimusten-
mukaisuusvakuutuksen
julkaisupaikka:** Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

Nous, le fabricant,

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

assurons et déclarons sous notre seule responsabilité que les dispositifs médicaux de classe I non stériles (conformément à la réglementation sur les dispositifs médicaux, MDR), non réutilisables et non destinés à la prise de mesures sont conformes aux dispositions relatives aux dispositifs médicaux de l'Annexe IV du règlement de l'UE sur les dispositifs médicaux 2017/745 (MDR) qui les concernent. Ces dispositifs sont conformes à la réglementation 2017/745 sur les dispositifs médicaux pour la délivrance de la déclaration de conformité UE. Tous les documents justificatifs sont conservés dans les locaux du fabricant.

Gamme de produits	Nom commercial du produit	Item Number	Code(s) produit	UDI-DI de base	Spécifications communes
Brosses de nettoyage	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS : 10-502 GMDN : 38835	084977100000000000000001M3	Il n'existe pas de spécifications communes établies par la Commission européenne dans le cadre du MDR s'appliquant au produit Key Surgical mentionné dans la présente déclaration. Les normes reconnues et mises en œuvre sont identifiées dans la documentation technique.
	Usage prévu : Nettoyage de dispositifs médicaux	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336		

09338
09339
09340
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09345
09346
09365
09366
09380
09388
09499
09745
09746
09747
AT-12-062
AT-12-062-50
AT-12-087
AT-12-087-50
AT-12-105
AT-12-105-50
AT-12-118
AT-12-118-50
AT-12-125
AT-12-125-50
AT-12-131
AT-12-131-50
AT-12-158
AT-12-158-50
AT-12-197
AT-12-197-50
AT-12-250
AT-12-250-50
AT-12-276
AT-12-276-50
AT-12-375
AT-12-375-50
AT-12-440
AT-12-440-50
AT-18-062
AT-18-062-50
AT-18-087
AT-18-087-50
AT-18-105
AT-18-105-50
AT-18-118
AT-18-118-50
AT-18-125
AT-18-125-50
AT-18-131
AT-18-131-50
AT-18-158
AT-18-158-50
AT-18-197
AT-18-197-50
AT-18-250
AT-18-250-50
AT-18-276
AT-18-276-50
AT-18-375
AT-18-375-50
AT-18-440
AT-18-440-50

AT-24-062
AT-24-062-50
AT-24-087
AT-24-087-50
AT-24-105
AT-24-105-50
AT-24-118
AT-24-118-50
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PC-200C

PC-212C
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	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118		

		BR-31-197 BR-31-276 BR-3201 BR-3201-50 BR-4140			
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR- 5200, BR-5400, BR- 5450, BR-5455, BR- 5500, BR-5600			
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325			
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50			

BR-075-24
BR-075-24-50
BR-075-32
BR-075-32-50
BR-075-42
BR-075-42-50
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BR-3420-50
BR-3701
BR-3702

		BR-3703 BR-3711-100 BR-3711-50 BR-3799-50 BR-3711			
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS : 21- 134 GMDN : 38835		
Canules d'irrigation Usage prévu : Irrigation des plaies.	Key Surgical Cannulas (non- sterile)	05001, 05003, 05005, 05007, 05009	UMDNS : 15- 206 GMDN : 62389	0849771000000000000002M5	
Protecteurs d'instruments Usage prévu : Protection et couverture d'instruments médicaux.	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06- 01, 01800, 3-06-02, I3- 06-02, 01801, 3-06-03, I3-06-03, 01802, 3-06- 04, I3-06-04, 01803, 3- 06-05, I3-06-05, 01804, 3-06-07, I3-06- 07, 01805, 3-11-01, I3- 11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11- 03, 01828, 3-11-04, I3- 11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11- 06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12- 01, 01838, 3-12-02, I3- 12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12- 06, 01843, 3-12-07, I3- 12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12- 09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14- 07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10- 04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3- 04-98, 3-04-99, 3-05- 02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05- 24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09- 03, 01814, 3-09-04, I3- 09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09- 08, I3-09-08, 01472, 01473, 3-09-09, 01474, 01475, 01494, 3-09-10, 3-24-98, 3-24-99, 3-48- 50, 3-80-03, 3-60-01, 3-60-02, 3-60-03, 3-60-	UMDNS : 16- 222 GMDN : 63247	0849771000000000000003M7	

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I3-03-02, I3-03-03, I3-
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	<p>Key Surgical Instrument Tip Protectors</p>	<p>PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457</p>			

<p>Protections pour broches et broches de Kirschner Usage prévu : Protection et couverture des broches et broches de Kirschner.</p>	<p>Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)</p>	<p>C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS</p>			
<p>Plateau de stérilisation d'instruments Usage prévu : Protection des dispositifs lors du nettoyage, de la stérilisation et du stockage.</p>	<p>Key Surgical Plastic Sterilization Trays Key Surgical Finger Mat Key Surgical Mesh Trays</p>	<p>PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB FM-1810 08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50</p>	<p>UMDNS :12-143 GMDN :13730</p>	<p>084977100000000000000004M9</p>	

		DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Protections d'angle pour plateaux Usage prévu : Protection des angles des plateaux de stérilisation et des enveloppes de stérilisation	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS : 15- 907 GMDN : 63494 & 65133	084977100000000000000005MB	
Dissolvant pour adhésif Usage prévu : Solution permettant d'éliminer les résidus d'adhésif des instruments médicaux	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN : 64150	084977100000000000000006MD	
Film thermique Usage prévu : À utiliser avec les méthodes de stérilisation à l'air chaud	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS : GMDN : 13735	084977100000000000000007MF	
Enveloppe de stérilisation Usage prévu : Enveloppe barrière stérile	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100	UMDNS : GMDN : 13735	084977100000000000000008MH	

CB/TWO120
CB/TWR120
CB/TWRAP060
CB/TWRAP075
CB/TWRAP090
CB/TWRAP100
CB/TWRAP1012
CB/TWRAP120
CB/TWRAP1315
CB/TWRAP1315X
CB/TWRAP150
CB/TWRAP150F3W
CB/TWRAP18135
CB/TWRAP1815
CB/TWRAP5075
CB/TWRAPDRY050
CB/TWRAPDRY060
CB/TWRAPDRY075
CB/TWRAPDRY090
CB/TWRAPDRY100
CB/TWRAPDRY120
CB/TWRAPDRY1315X
CB/TWRAPDRY140
CB/TWY100
CB/TWY120
CB030
CB050
CB060
CB075
CB090
CB100
CB100DB
CB1012
CB1014
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CB120DB
CB1315
CB1315DB
CB140
CB150
CB1540
CB1715
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CB1815
CB1815DB
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CBA/TWRAP140
CBA050
CBA075
CBA090
CBA100
CBA120
CBA1415
CBU/TWRAP100
CBU/TWRAP1215
CBU/TWRAP1315
CBU/TWY120
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CDB/CG075
CDB/CG075DB

CDB/CG090
CDB/CG100
CDB/CG1012
CDB/CG1012DB
CDB/CG1014
CDB/CG120
CDB/CG120DB
CDB/CG1215
CDB/CG1215DB
CDB/CG1315
CDB/CG1315DB
CDB/CG140
CDB/CG150
CDB/CG150DB
CDB/CG1815
CDB/CG1815DB
CDB/GC120
CDB/GC140
CDB/TWO090
CDB/TWR120
CDB/TWRAP090
CDB/TWRAP100
CDB140
CDB1815
CDB5075
CDG/CB060
CDG/CB075
CDG/CB075DB
CDG/CB090
CDG/CB100
CDG/CB1012DB
CDG/CB1015
CDG/CB120
CDG/CB120DB
CDG/CB1215DB
CDG/CB1315
CDG/CB1315DB
CDG/CB1815DB
CDG/TWO1215
CDG/TWO1315X
CDG/TWRAP060
CDG/TWRAP075
CDG/TWRAP090
CDG/TWRAP100
CDG/TWRAP100DB
CDG/TWRAP1014
CDG/TWRAP120
CDG/TWRAP120DB
CDG/TWRAP1214
CDG/TWRAP1215
CDG/TWRAP1315
CDG/TWRAP150
CDG/TWY1315
CDG075
CDG090
CDG100
CDG120
CDG1215
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CDG150
CDG1815
CG/CB050
CG/CB060
CG/CB075
CG/CB075DB

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CG/CB100DB
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CG/CB140X
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CG/CBU090
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CG/CBU100DB
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CG/CBU1090
CG/CBU1215
CG/CBU1315DB
CG/CBU1315X
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CG/PRO1815
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CG/TWY090
CG/TWY090DB
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CG/TWY100DB
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CG/TWY1012DB
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CG/TWY1090DB
CG/TWY1215

CG/TWY1215PZDB
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CG/TWY1315DB
CG/TWY1815
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CG/WB1315
CG/WB1815
CG060
CG075
CG075DB
CG090
CG090/P150
CG100
CG100/P150
CG100DB
CG120
CG120DB
CG1215
CG1315
CG140
CG150
CG1715DB
CG1815DB
CG5075
CGP/CB100
CGP/CB120
CGP/CB1715
CGP/CB1815
CGP/CBU100
CGP/CBU1014
CGP/CBU1014DB
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CGP/CBU1215
CGP/CBU1315
CGP/CBU140
CGP/CBU1815
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CGP/TWO1012
CGP/TWO1215
CGP/TWO1815
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CGP/TWRAP1075
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CGP/TWY075
CGP/TWY100
CGP/TWY1315
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CGP150
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CGX/CB075DB
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CGX/TWRAP075DB
CGX/TWRAP090
CGX/TWRAP090DB
CGX/TWRAP100
CGX/TWRAP100DB
CGX/TWRAP1012
CGX/TWRAP1012DB
CGX/TWRAP1090DB
CGX/TWRAP1215
CGX/TWRAP1215PZDB
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CGX/TWRAP1715DB
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CGX/TWRAPDRY1315
CGX/TWY090DB
CGX/TWY1012DB
CGX/TWY1090DB
CGX/TWY1215PZDB
CGX/TWY1315
CGX/TWY1315DB
CGX090
CGX100

CGX100DB
 CGX120
 CGX1715DB
 REL340G/CBU100
 REL340G/CBU1014
 REL340G/CBU1215
 REL340G/CBU1315
 RELGRN/CB100
 RELGRN/CB1050
 RELGRN/CB1315
 RELGRN/CB140
 RELGRN/WB1815
 WB/TDRY100DB
 WB/TWO075
 WB/TWO1012
 WB/TWO1014
 WB/TWO1014DB
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 WB/TWRAP075
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 WB/TWRAPDRY060
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 WB/TWRAPDRY100
 WB/TWRAPDRY120
 WB/TWRAPDRY1315X
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 WB/TWRAPDRY150F3
 WB/TWY090
 WB/TWY1014
 WB/TWY1215
 WB075
 WB090
 WB100
 WB1014
 WB120
 WB140
 CBA060
 CBU140
 CDG1315
 CG/TWRAPDRY060
 CGX/TWY1215
 WB/TWRAPDRY1012
 MC-CBA/TWRAP090
 MC-CBA/TWRAP100
 MC-CBA/TWRAP120
 RELGRN/CBU100
 RELGRN/CBU140
 CG/CBU120
 CGX/TWY090
 CGX/TWY1012
 CG/CBU1815
 CB/TDRY075
 CB/TDRY090
 CB/TDRY100
 CB/TDRY060

		CB/TDRY120 CGX/TWR1815			
<p>Enveloppe de transport</p> <p>Usage prévu : Enveloppe barrière de transport</p>	<p>Transportation wrap and covers</p>	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB TWRAP1014 TWRAP1090DB	GMDN : 13735	0849771000000000000009MK	

TWRAP120
TWRAP1215
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TWRAP140DB
TWRAP150
TWRAP150DB
TWRAP1715
TWRAP1715DB
TWRAP1815
TWRAP1815DB
TWRAP5090
TWRAP5390
TWRAP7537
TWRAP75375
TWRAPDRY050
TWRAPDRY060
TWRAPDRY075
TWRAPDRY090
TWRAPDRY100
TWRAPDRY1012
TWRAPDRY1014
TWRAPDRY120
TWRAPDRY1315
TWRAPDRY140
TWRAPDRY1815
TWRAPDRY3015
TWRAPDRY3015SGL
TWRAPDRY5075
TWRAPDRY7560
TWRAPDRYOFFCUT
TWY075
TWY075DB
TWY090
TWY100
TWY100DB
TWY1012
TWY1014
TWY120
TWY1215
TWY1215DB
TWY1315
TWY1315DB
TWY140
TWY1715
TWY1715DB
TWY1815
CDBAG002G
H-THCOVER001
H-THCOVER002
H-THCOVER003
H-THOCOVER001
H-THOCOVER002
H-THOCOVER003
H-THRCOVER001
H-THRCOVER002
H-THRCOVER003
H-THYCOVER001
H-THYCOVER002
H-THYCOVER003
PC000700
PC000800
PC000900

		PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Enveloppe de transport Usage prévu : Enveloppe barrière de transport	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN : 13735		
Filtres pour récipients Usage prévu : À utiliser avec des récipients de stérilisation.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157 01158	GMDN : 60909	0849771000000000000010M4	

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1070020
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55-291-01-04
61140
71140
71141
71194
91140
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ME01194
ME26515
ME27325
ME27335

		ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Feuilles de protection pour plateaux Usage prévu : Stérilisation des dispositifs médicaux.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007 H-TLC008 H-TLC009 H-TLC010 H-TLC011 H-TLC012 H-TLC013 H-TLC078 H-TLC109 H-TLC110 H-TLC111 H-TLC119 H-TLC213 H-TLC214 H-TLC215 LIB1328 LIB250X320 LIB300X360 LIB300X500 LIB3025 LIB3050 LIB400X500 LINH3020 LINH3041 LINH4555 MILB002 MILB003 MILB004 MILB005 MILB006 MILB007 MILB008 MILB009 MILB011 MILB012 MILB016 MILB017	GMDN : 60908		0849771000000000000011M6

MILB019
MILB020
MILB021
MILB022
MILB025
MILB027
MILB029
MILB056
MILB120X250
MILB130X230
MILB170X270
MILB250X300
MILB300X400
MILB305X450
MILB350x450
MILB375X600
MILB450X650
MILB500X900
PC002100
PC002200
PC008800
PC008900
PC009000
PC009100
PC009200
PC009400
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PC009900
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PC011200
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PC011800
PC013300
PC013600
TL-101-200
TL-202-500
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TLC001
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	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300 PC013100 PC013200	GMDN : 61664		

		SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Huile d'entretien Usage prévu : Lubrification des dispositifs médicaux.	Lubrinol / Enginol	02004 02006 02005	GMDN : 15772	0849771000000000000012M8	
Chiol Ultra Usage prévu : Solution de nettoyage permettant d'éliminer les saletés des surfaces métalliques.	Chiol Ultra	02110	GMDN : 63385	0849771000000000000013MA	

Nous désignons par la présente

Medical Device Safety Service (MDSS)
Schiffgraben 41
D-30175 Hanovre
Allemagne

représentant européen autorisé, tel que défini à l'Article 2(32) du MDR.

Déroulement de l'évaluation de la conformité : Annexe IV

Délivré par :

Signature :



Date : 2021-12-28

Nom :

Coletta Cohara

Titre :

Directeur de la qualité et de la conformité
réglementaire

**Lieu de délivrance de
la déclaration de
conformité :**

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

IT - Dichiarazione di conformità

Il fabbricante,

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

garantisce e dichiara, sotto la sua esclusiva responsabilità, che i seguenti dispositivi medici di Classe I non sterili (in conformità al MDR), non riutilizzabili e non di misurazione sono conformi alle disposizioni del Regolamento europeo per i dispositivi medici 2017/745 (European Medical Devices Regulation - MDR), Allegato IV per i dispositivi medici, ad essi applicabili. Questi dispositivi sono conformi al Regolamento per i dispositivi medici 2017/745 che prevede il rilascio di una dichiarazione di conformità UE. Tutta la documentazione di supporto è conservata presso il fabbricante.

Famiglia di prodotti	Nome commerciale del prodotto	Item Number	Codice/i prodotto	UDI-DI di base	Specifiche comuni
Pennelli per la pulizia Scopo previsto: pulizia di dispositivi medici	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	08497710000000000000000001M3	Nella presente dichiarazione non vi sono specifiche comuni stabilite dalla Commissione Europea ai sensi del MDR applicabili al prodotto Key Surgical. Gli standard riconosciuti applicati sono identificati nella documentazione tecnica.
	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336 09338	UMDNS: 21-134 GMDN: 34878 & 38835		

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09747
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AT-12-197
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AT-12-276-50
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AT-12-440
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AT-18-062
AT-18-062-50
AT-18-087
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AT-18-118
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H-FLEX033
H-FLEX034
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H-FLEXSAMP
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MED100.62
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MJ-370C-1
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PC-112C
PC-200C
PC-212C

PC-300P
PC-306P
PC-312P
PC-400P
PC-412P
PC-503
PC-512
PC-515
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PP-22-125-50
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PP-22-197-50
PP-24-250-50
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BR-06-039
PP-22-039
PP-22-062
PP-22-087
PP-22-105
PP-22-125
PP-22-158
PP-22-197
PP-24-250
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PT-28-197
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FLEX026
BR-18-591
BR-18-880
BR-24-070
BR-24-080
BR-24-098
BR-24-197
BR-24-200
BR-24-236
BR-24-276
BR-24-312

		BR-24-375 BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4 96281.7 MED100.98 26474 26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197			

		BR-31-276 BR-3201 BR-3201-50 BR-4140		
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600		
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325		
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50 BR-075-24		

BR-075-24-50
BR-075-32
BR-075-32-50
BR-075-42
BR-075-42-50
BR-075-99
BR-100-18
BR-100-18-50
BR-100-24
BR-100-24-50
BR-100-32
BR-100-32-50
BR-100-42
BR-100-42-50
BR-100-99,
BR-150-18
BR-150-18-50
BR-150-24
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BR-150-32
BR-150-32-50
BR-150-42
BR-150-42-50
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BR-200-32-50
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BR-3305
BR-3307
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BR-3309
BR-3309-50
BR-3310
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BR-3340
BR-3340-50
BR-3399
BR-3410
BR-3410-50
BR-3420
BR-3420-50
BR-3701
BR-3702
BR-3703

		BR-3711-100 BR-3711-50 BR-3799-50 BR-3711		
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21-134 GMDN: 38835	
Cannule di irrigazione Scopo previsto: destinato all'uso per l'irrigazione della ferita.	Key Surgical Cannulas (non-sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15-206 GMDN: 62389	0849771000000000000002M5
Protezioni strumenti Scopo previsto: destinate a coprire e proteggere strumenti medicali.	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06-01, 01800, 3-06-02, I3-06-02, 01801, 3-06-03, I3-06-03, 01802, 3-06-04, I3-06-04, 01803, 3-06-05, I3-06-05, 01804, 3-06-07, I3-06-07, 01805, 3-11-01, I3-11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11-03, 01828, 3-11-04, I3-11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12-01, 01838, 3-12-02, I3-12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, I3-12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12-09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10-04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09-03, 01814, 3-09-04, I3-09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09-08, I3-09-08, 01472, 01473, 3-09-09, 01474, 01475, 01494, 3-09-10, 3-24-98, 3-24-99, 3-48-50, 3-	UMDNS: 16-222 GMDN: 63247	0849771000000000000003M7

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Guaine per filo K e perni		48-13, 3-48-15, 3-48-16,3-48-17, 3-48-18, 3-48-19, 3-74-11, 3-74-15, 3-78-11, I3-04-11, I3-04-12, I3-04-13, I3-04-15, I3-04-18, 3-04-07, 01480, 3-04-08, 01481, 3-04-09, 01482, 01810, 3-08-07, 01466, 3-08-08, 01467, 3-08-09, 01468, 3-15-07, 01887, 3-15-08, 01888, 3-15-09, 01889, 3-24-08, 3-24-09, 3-44-07, 3-44-08, 3-44-09, 3-48-07, 3-48-08, 3-48-09, 3-74-07, 3-74-09, I3-04-07, I3-04-08, I3-04-09, I3-08-07, I3-08-08, I3-08-09, 3-01-07, 3-01-08, 01824, 3-01-09, 3-02-07, 01879, 3-02-08, 3-02-09, 3-03-07, 3-03-08, 3-03-09, 3-16-05, 3-16-06, 3-16-07, 3-16-08, 01821, 3-16-09, 30000, 30001, 30002, 30003, 30004, 30005, 30006, 30007,30008, 30009, 30010, 30012, 30013, 30014, 30015, 30016, 30017, 01850, 01851, 01852, 01853, 01854, TP-09-11, TP-09-12, TP-09-13, 3-02-05, 3-04-15 3-06-50 3-08-09 3-08-100 3-11-01 01826			
	Key Surgical Instrument Tip Protectors	PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457			

Scopo previsto: proteggere e coprire fili K e perni.	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS			
Vassoio per sterilizzazione di strumenti Scopo previsto: protezione di dispositivi durante la pulizia, la sterilizzazione e la conservazione.	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS:12-143 GMDN:13730	08497710000000000000004M9	
	Key Surgical Finger Mat	FM-1810			
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50 DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			

	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Protezioni angolari per vassoio Scopo previsto: protezione degli angoli del vassoio di sterilizzazione e degli involucri per sterilizzazione	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15-907 GMDN: 63494 & 65133		0849771000000000000005MB
Solvente per adesivi Scopo previsto: soluzione per la rimozione di residui adesivi da strumenti medicali	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN:64150		0849771000000000000006MD
Pellicola ad aria calda Scopo previsto: indicata per l'uso con metodi di sterilizzazione ad aria calda	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735		0849771000000000000007MF
Involucri per sterilizzazione Scopo previsto: telo barriera sterile	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100 CB/TWO120 CB/TWR120 CB/TWRAP060 CB/TWRAP075 CB/TWRAP090 CB/TWRAP100 CB/TWRAP1012 CB/TWRAP120 CB/TWRAP1315 CB/TWRAP1315X CB/TWRAP150 CB/TWRAP150F3W CB/TWRAP18135 CB/TWRAP1815	UMDNS: GMDN: 13735		0849771000000000000008MH

CB/TWRAP5075
CB/TWRAPDRY050
CB/TWRAPDRY060
CB/TWRAPDRY075
CB/TWRAPDRY090
CB/TWRAPDRY100
CB/TWRAPDRY120
CB/TWRAPDRY1315X
CB/TWRAPDRY140
CB/TWY100
CB/TWY120
CB030
CB050
CB060
CB075
CB090
CB100
CB100DB
CB1012
CB1014
CB120
CB120DB
CB1315
CB1315DB
CB140
CB150
CB1540
CB1715
CB1715DB
CB1815
CB1815DB
CBA/TWRAP120
CBA/TWRAP140
CBA050
CBA075
CBA090
CBA100
CBA120
CBA1415
CBU/TWRAP100
CBU/TWRAP1215
CBU/TWRAP1315
CBU/TWY120
CBU1014
CBU1014DB
CBU120
CBU1315
CBU150
CDB/CG060
CDB/CG075
CDB/CG075DB
CDB/CG090
CDB/CG100
CDB/CG1012
CDB/CG1012DB
CDB/CG1014
CDB/CG120
CDB/CG120DB
CDB/CG1215
CDB/CG1215DB
CDB/CG1315
CDB/CG1315DB
CDB/CG140
CDB/CG150
CDB/CG150DB

CDB/CG1815
CDB/CG1815DB
CDB/GC120
CDB/GC140
CDB/TWO090
CDB/TWR120
CDB/TWRAP090
CDB/TWRAP100
CDB140
CDB1815
CDB5075
CDG/CB060
CDG/CB075
CDG/CB075DB
CDG/CB090
CDG/CB100
CDG/CB1012DB
CDG/CB1015
CDG/CB120
CDG/CB120DB
CDG/CB1215DB
CDG/CB1315
CDG/CB1315DB
CDG/CB1815DB
CDG/TWO1215
CDG/TWO1315X
CDG/TWRAP060
CDG/TWRAP075
CDG/TWRAP090
CDG/TWRAP100
CDG/TWRAP100DB
CDG/TWRAP1014
CDG/TWRAP120
CDG/TWRAP120DB
CDG/TWRAP1214
CDG/TWRAP1215
CDG/TWRAP1315
CDG/TWRAP150
CDG/TWY1315
CDG075
CDG090
CDG100
CDG120
CDG1215
CDG140
CDG150
CDG1815
CG/CB050
CG/CB060
CG/CB075
CG/CB075DB
CG/CB090
CG/CB100
CG/CB100DB
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CG/CB1014
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CG/CBU1215
CG/CBU1315DB
CG/CBU1315X
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CG/TWO1715DB
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CG/TWRAPDRY1090
CG/TWRAPDRY120
CG/TWRAPDRY120DB
CG/TWRAPDRY1215
CG/TWRAPDRY1315
CG/TWRAPDRY1315D
CG/TWRAPDRY1315X
CG/TWRAPDRY140
CG/TWRAPDRY150
CG/TWRAPDRY1715
CG/TWRAPDRY1815
CG/TWRAPDRY1815M
CG/TWY060
CG/TWY075DB
CG/TWY090
CG/TWY090DB
CG/TWY100
CG/TWY100DB
CG/TWY1012
CG/TWY1012DB
CG/TWY1090
CG/TWY1090DB
CG/TWY1215
CG/TWY1215PZDB
CG/TWY1315
CG/TWY1315DB
CG/TWY1815
CG/WB120
CG/WB1315
CG/WB1815
CG060
CG075
CG075DB
CG090
CG090/P150
CG100
CG100/P150

CG100DB
CG120
CG120DB
CG1215
CG1315
CG140
CG150
CG1715DB
CG1815DB
CG5075
CGP/CB100
CGP/CB120
CGP/CB1715
CGP/CB1815
CGP/CBU100
CGP/CBU1014
CGP/CBU1014DB
CGP/CBU1090
CGP/CBU1215
CGP/CBU1315
CGP/CBU140
CGP/CBU1815
CGP/TWO100
CGP/TWO1012
CGP/TWO1215
CGP/TWO1815
CGP/TWRAP060
CGP/TWRAP060DB
CGP/TWRAP075
CGP/TWRAP075DB
CGP/TWRAP090
CGP/TWRAP100
CGP/TWRAP1012
CGP/TWRAP1075
CGP/TWRAP120
CGP/TWRAP1215
CGP/TWRAP1315
CGP/TWRAP150
CGP/TWRAP1815
CGP/TWY075
CGP/TWY100
CGP/TWY1315
CGP/TWY1815
CGP1315
CGP150
CGX/CB075
CGX/CB075DB
CGX/CB090
CGX/CB100
CGX/CB100DB
CGX/CB1012
CGX/CB1012DB
CGX/CB1014
CGX/CB1090
CGX/CB1090DB
CGX/CB1215
CGX/CB1215DB
CGX/CB1315
CGX/CB1315/P120
CGX/CB1315P120DB
CGX/CB1715
CGX/CB1715DB
CGX/CB1815
CGX/CB1815DB
CGX/CB5075

CGX/CB5075DB
CGX/CBU060
CGX/CBU060DB
CGX/CBU100
CGX/CBU1012
CGX/CBU1014
CGX/CBU1014DB
CGX/CBU1090
CGX/CBU1090DB
CGX/CBU1215
CGX/CBU1315
CGX/CBU1315DB
CGX/CBU1815
CGX/TWO1012DB
CGX/TWO1090DB
CGX/TWO1215PZDB
CGX/TWO1315
CGX/TWR1090DB
CGX/TWR1215PZDB
CGX/TWR1715DB
CGX/TWRAP075DB
CGX/TWRAP090
CGX/TWRAP090DB
CGX/TWRAP100
CGX/TWRAP100DB
CGX/TWRAP1012
CGX/TWRAP1012DB
CGX/TWRAP1090DB
CGX/TWRAP1215
CGX/TWRAP1215PZDB
CGX/TWRAP1315
CGX/TWRAP1315PZDB
CGX/TWRAP1715DB
CGX/TWRAP1815
CGX/TWRAP1815DB
CGX/TWRAP5075
CGX/TWRAP5075DB
CGX/TWRAPD100DB
CGX/TWRAPD1215DB
CGX/TWRAPD1315DB
CGX/TWRAPDRY100
CGX/TWRAPDRY1215
CGX/TWRAPDRY1315
CGX/TWY090DB
CGX/TWY1012DB
CGX/TWY1090DB
CGX/TWY1215PZDB
CGX/TWY1315
CGX/TWY1315DB
CGX090
CGX100
CGX100DB
CGX120
CGX1715DB
REL340G/CBU100
REL340G/CBU1014
REL340G/CBU1215
REL340G/CBU1315
RELGRN/CB100
RELGRN/CB1050
RELGRN/CB1315
RELGRN/CB140
RELGRN/WB1815
WB/TDRY100DB
WB/TWO075

		WB/TWO1012 WB/TWO1014 WB/TWO1014DB WB/TWO1315 WB/TWRAP060 WB/TWRAP075 WB/TWRAP090 WB/TWRAP100 WB/TWRAP100DB WB/TWRAP1012 WB/TWRAP1014DB WB/TWRAP1075 WB/TWRAP1215 WB/TWRAP1215DB WB/TWRAP1315 WB/TWRAP1815 WB/TWRAPDRY060 WB/TWRAPDRY090 WB/TWRAPDRY100 WB/TWRAPDRY120 WB/TWRAPDRY1315X WB/TWRAPDRY150 WB/TWRAPDRY150F3 WB/TWY090 WB/TWY1014 WB/TWY1215 WB075 WB090 WB100 WB1014 WB120 WB140 CBA060 CBU140 CDG1315 CG/TWRAPDRY060 CGX/TWY1215 WB/TWRAPDRY1012 MC-CBA/TWRAP090 MC-CBA/TWRAP100 MC-CBA/TWRAP120 RELGRN/CBU100 RELGRN/CBU140 CG/CBU120 CGX/TWY090 CGX/TWY1012 CG/CBU1815 CB/TDRY075 CB/TDRY090 CB/TDRY100 CB/TDRY060 CB/TDRY120 CGX/TWR1815			
Telo di trasporto Scopo previsto: telo barriera di trasporto	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120	GMDN: 13735	0849771000000000000009MK	

TDRY3024
TDRYPACK1012
TDRYPACK1815
TWO050
TWO060
TWO075
TWO075DB
TWO090
TWO100
TWO1012
TWO1012DB
TWO1014
TWO120
TWO1215
TWO1215DB
TWO1315
TWO140
TWO140DB
TWO150
TWO150DB
TWO1715DB
TWO1815
TWO5075
TWR060
TWR075
TWR075DB
TWR090
TWR100
TWR100DB
TWR1012DB
TWR1014
TWR1090DB
TWR120
TWR1215DB
TWR1315
TWR140
TWR150
TWR1715DB
TWR1815
TWR5075DB
TWRAP050
TWRAP060
TWRAP075
TWRAP075DB
TWRAP090
TWRAP100
TWRAP100DB
TWRAP1012
TWRAP1012DB
TWRAP1014
TWRAP1090DB
TWRAP120
TWRAP1215
TWRAP1215DB
TWRAP1315
TWRAP1315DB
TWRAP140
TWRAP140DB
TWRAP150
TWRAP150DB
TWRAP1715
TWRAP1715DB
TWRAP1815
TWRAP1815DB
TWRAP5090

TWRAP5390
TWRAP7537
TWRAP75375
TWRAPDRY050
TWRAPDRY060
TWRAPDRY075
TWRAPDRY090
TWRAPDRY100
TWRAPDRY1012
TWRAPDRY1014
TWRAPDRY120
TWRAPDRY1315
TWRAPDRY140
TWRAPDRY1815
TWRAPDRY3015
TWRAPDRY3015SGL
TWRAPDRY5075
TWRAPDRY7560
TWRAPDRYOFFCUT
TWY075
TWY075DB
TWY090
TWY100
TWY100DB
TWY1012
TWY1014
TWY120
TWY1215
TWY1215DB
TWY1315
TWY1315DB
TWY140
TWY1715
TWY1715DB
TWY1815
CDBAG002G
H-THCOVER001
H-THCOVER002
H-THCOVER003
H-THOCOVER001
H-THOCOVER002
H-THOCOVER003
H-THRCOVER001
H-THRCOVER002
H-THRCOVER003
H-THYCOVER001
H-THYCOVER002
H-THYCOVER003
PC000700
PC000800
PC000900
PC011500
PC011600
TCOVER001
TCOVER002
TCOVER003
TCOVER007
TCOVER008
TCOVERDRY001
TCOVERDRY002
TCOVERDRY003
TCOVER-RED001
TCOVER-RED002
TCOVER-RED003
TCOVER-YELL001

		TCOVER-YELL002 TCOVER-YELL003			
Telo di trasporto Scopo previsto: telo barriera di trasporto	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN: 13735		
Filtri contenitore Scopo previsto: per l'uso con contenitori di sterilizzazione.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157 01158 01167 01168 01181 01183 01186 01188 01189 01194 01196 01198 01300 01304 01306 01312	GMDN: 60909	0849771000000000000010M4	

		01314 01315 01317 01318 01319 01321 01322 01323 01327 01330 01331 01332 01346 01347 01348 01350 01355 01356 01363 01365 01366 01367 01368 01369 01373 04111 1070020 26510 27320 27330 27340 27350 27360 55-291-01-04 61140 71140 71141 71194 91140 26515 27325 27335 27345 27355 27365 91140 26510 ME01194 ME26515 ME27325 ME27335 ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Rivestimenti per vassoio	Tray Liners	49937 49938 50110 51448 1136011	GMDN:60908	0849771000000000000011M6	

Scopo previsto:
per l'uso nella
sterilizzazione
di dispositivi
medici.

1137011
CBL003
CBL300X300H
CBL350X350
CBL400X400
CBL400X600
CBL500X700
CBL580X350
H-CBL001
H-CBL002
H-CBL003
H-TLC004
H-TLC005
H-TLC006
H-TLC007
H-TLC008
H-TLC009
H-TLC010
H-TLC011
H-TLC012
H-TLC013
H-TLC078
H-TLC109
H-TLC110
H-TLC111
H-TLC119
H-TLC213
H-TLC214
H-TLC215
LIB1328
LIB250X320
LIB300X360
LIB300X500
LIB3025
LIB3050
LIB400X500
LINH3020
LINH3041
LINH4555
MILB002
MILB003
MILB004
MILB005
MILB006
MILB007
MILB008
MILB009
MILB011
MILB012
MILB016
MILB017
MILB019
MILB020
MILB021
MILB022
MILB025
MILB027
MILB029
MILB056
MILB120X250
MILB130X230
MILB170X270
MILB250X300
MILB300X400
MILB305X450

		MILB350x450 MILB375X600 MILB450X650 MILB500X900 PC002100 PC002200 PC008800 PC008900 PC009000 PC009100 PC009200 PC009400 PC009800 PC009900 PC010000 PC010200 PC010400 PC010700 PC010800 PC011200 PC011300 PC011400 PC011700 PC011800 PC013300 PC013600 TL-101-200 TL-202-500 TL-203-500 TL-204-500 TLC001 TLC002 TLC004 TLC005 TLC006 TLC007 TLC008 TLC009 TLC010 TLC011 TLC012 TLC013 TLC014 TLC017 TLC018 TLC019 TLC020 TLC022 TLC023 TLC024 TLC027 TLC029R TLC030 TLC031 TLC034 TLC036 TLC045 TLC051 TLC052 TLC055 TLC060 TLC066 TLC069 TLC071 TLC072			
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		TLC078 TLC079 TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300 PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS	GMDN:61664		

		SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Olio di manutenzione					
Scopo previsto: indicato per l'uso nella lubrificazione di dispositivi medici.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	0849771000000000000012M8	
Chirol Ultra					
Scopo previsto: soluzione detergente per la rimozione di sporcizia da superfici metalliche.	Chirol Ultra	02110	GMDN: 63385	08497710000000000000013MA	

Con la presente nominiamo

Medical Device Safety Service (MDSS)
Schiffgraben 41
D-30175 Hannover
Germania

Rappresentante autorizzato per l'Europa, come previsto dall'articolo 2 (32) del MDR.

Procedura di valutazione della conformità: Allegato IV

Rilasciato da:

Firma:



Data: 2021-12-28

Nome:

Coletta Cohara

Posizione:

Responsabile della qualità e della conformità alle normative

Luogo di rilascio della Dichiarazione di conformità:

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

NL - Verklaring van overeenstemming

Wij, de fabrikant,

Key Surgical LLC
 8101 Wallace Rd.
 Eden Prairie, MN 55344
 USA

zorgen ervoor en verklaren dat de volgende klasse I niet steriele medische hulpmiddelen (volgens MDR), niet herbruikbare, medische hulpmiddelen die geen meetinstrumenten zijn, voldoen aan de bepalingen van de EU-verordening inzake medische hulpmiddelen 2017/745 (MDR) bijlage IV voor medische hulpmiddelen die daarop van toepassing zijn. Deze hulpmiddelen zijn in overeenstemming met de verordening inzake medische hulpmiddelen 2017/745 die voorziet in de afgifte van de EU-conformiteitsverklaring. Alle ondersteunende documentatie blijft bewaard op de bedrijfslocatie van de fabrikant.

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
Reinigingsborstels Beoogd doel: reinigen van medische hulpmiddelen	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	084977100000000000000001M3	Er zijn geen gemeenschappelijke specificaties uiteengezet door de Europese Commissie onder MDR die van toepassing zijn op het product van Key Surgical in deze verklaring. De toegepaste erkende normen worden in de technische documentatie geïdentificeerd.
	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336	UMDNS: 21-134 GMDN: 34878 en 38835		

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		09338			
		09339			
		09340			
		09341			
		09342			
		09343			
		09344			
		09345			
		09346			
		09365			
		09366			
		09380			
		09388			
		09499			
		09745			
		09746			
		09747			
		AT-12-062			
		AT-12-062-50			
		AT-12-087			
		AT-12-087-50			
		AT-12-105			
		AT-12-105-50			
		AT-12-118			
		AT-12-118-50			
		AT-12-125			
		AT-12-125-50			
		AT-12-131			
		AT-12-131-50			
		AT-12-158			
		AT-12-158-50			
		AT-12-197			
		AT-12-197-50			
		AT-12-250			
		AT-12-250-50			
		AT-12-276			
		AT-12-276-50			
		AT-12-375			
		AT-12-375-50			
		AT-12-440			
		AT-12-440-50			
		AT-18-062			
		AT-18-062-50			
		AT-18-087			
		AT-18-087-50			
		AT-18-105			
		AT-18-105-50			
		AT-18-118			
		AT-18-118-50			
		AT-18-125			
		AT-18-125-50			
		AT-18-131			
		AT-18-131-50			
		AT-18-158			
		AT-18-158-50			
		AT-18-197			
		AT-18-197-50			
		AT-18-250			
		AT-18-250-50			
		AT-18-276			
		AT-18-276-50			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		AT-18-375			
		AT-18-375-50			
		AT-18-440			
		AT-18-440-50			
		AT-24-062			
		AT-24-062-50			
		AT-24-087			
		AT-24-087-50			
		AT-24-105			
		AT-24-105-50			
		AT-24-118			
		AT-24-118-50			
		AT-24-125			
		AT-24-125-50			
		AT-24-131			
		AT-24-131-50			
		AT-24-158			
		AT-24-158-50			
		AT-24-197			
		AT-24-197-50			
		AT-24-250			
		AT-24-250-50			
		AT-24-276			
		AT-24-276-50			
		AT-24-375			
		AT-24-375-50			
		AT-24-440			
		AT-24-440-50			
		B-2100-50			
		BBR001			
		BBR002			
		BBR003			
		BR-04-003			
		BR-04-003-50			
		BR-04-080			
		BR-04-080-50			
		BR-06-039-50			
		BR-06-062			
		BR-06-062-50			
		BR-06-079			
		BR-06-079-50			
		BR-06-250			
		BR-06-250-50			
		BR-06-375			
		BR-06-375-50			
		BR-06-500			
		BR-06-500-50			
		BR-07-075			
		BR-07-075-50			
		BR-07-107			
		BR-07-107-50			
		BR-08-039			
		BR-08-039-50			
		BR-08-070			
		BR-08-070-50			
		BR-08-079			
		BR-08-079-50			
		BR-08-087			
		BR-08-087-50			
		BR-08-092			
		BR-08-092-50			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		BR-08-105			
		BR-08-105-50			
		BR-08-118			
		BR-08-118-50			
		BR-08-131			
		BR-08-131-50			
		BR-08-144			
		BR-08-144-50			
		BR-08-158			
		BR-08-158-50			
		BR-08-250			
		BR-08-250-50			
		BR-08-440			
		BR-08-440-50			
		BR-08-630			
		BR-08-630-50			
		BR-12-079			
		BR-12-079-50			
		BR-12-118			
		BR-12-118-50			
		BR-12-158			
		BR-12-158-50			
		BR-12-197			
		BR-12-197-50			
		BR-12-236			
		BR-12-236-50			
		BR-16-197			
		BR-16-197-50			
		BR-16-236			
		BR-16-236-50			
		BR-16-276			
		BR-16-276-50			
		BR-16-393			
		BR-16-393-50			
		BR-16-443			
		BR-16-443-50			
		BR-16-472			
		BR-16-472-50			
		BR-16-591			
		BR-16-591-50			
		BR-16-787			
		BR-16-787-50			
		BR-18-039			
		BR-18-039-50			
		BR-18-062			
		BR-18-062-50			
		BR-18-070			
		BR-18-070-50			
		BR-18-087			
		BR-18-087-50			
		BR-18-105			
		BR-18-105-50			
		BR-18-125			
		BR-18-125-50			
		BR-18-158			
		BR-18-158-50			
		BR-18-197			
		BR-18-197-50			
		BR-18-250			
		BR-18-250-50			
		BR-18-393			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		BR-18-393-50			
		BR-18-591-50			
		BR-18-880-50			
		BR-2300			
		BR-24-070-50			
		BR-24-080-50			
		BR-24-098-50			
		BR-24-197-50			
		BR-24-200-50			
		BR-24-236-50			
		BR-24-276-50			
		BR-24-312-50			
		BR-24-375-50			
		BR-24-393-50			
		BR-24-425-50			
		BR-24-440-50			
		BR-24-443-50			
		BR-24-880-50			
		BR-4199			
		BR-4299			
		BR-4399			
		BR-4499			
		BR-4599			
		BR-4699			
		BR-4799			
		BR-4899			
		BR-4999			
		BR-5099			
		BR-5199C			
		BR-6099			
		BR-8110			
		BR-8110-50			
		BR-8115			
		BR-8115-50			
		BR-8210			
		BR-8210-50			
		BR-8310			
		BR-8310-50			
		BR-8315			
		BR-8315-50			
		BR-8410			
		BR-8410-50			
		BZ-06-2550			
		BZ-06-2550-50			
		BZ-08-125			
		BZ-08-125-50			
		BZ-10-050			
		BZ-10-050-50			
		BZ-12-062			
		BZ-12-062-50			
		BZ-12-087			
		BZ-12-087-50			
		BZ-12-098			
		BZ-12-098-50			
		BZ-12-125			
		BZ-12-125-50			
		BZ-12-158			
		BZ-12-158-50			
		BZ-16-250			
		BZ-16-250-50			
		BZ-18-062			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		BZ-18-062-50			
		BZ-18-079			
		BZ-18-079-50			
		BZ-18-1000			
		BZ-18-1000-50			
		BZ-18-105			
		BZ-18-105-50			
		BZ-18-125			
		BZ-18-125-50			
		BZ-18-131			
		BZ-18-131-50			
		BZ-18-144			
		BZ-18-144-50			
		BZ-18-1543			
		BZ-18-1543-50			
		BZ-18-158			
		BZ-18-158-50			
		BZ-18-197			
		BZ-18-197-50			
		BZ-18-236			
		BZ-18-236-50			
		BZ-18-250			
		BZ-18-250-50			
		BZ-18-312			
		BZ-18-312-50			
		BZ-18-354			
		BZ-18-354-50			
		BZ-18-393			
		BZ-18-393-50			
		BZ-18-433			
		BZ-18-433-50			
		BZ-18-472			
		BZ-18-472-50			
		BZ-24-125			
		BZ-24-125-50			
		FLEX001			
		FLEX002			
		FLEX003			
		FLEX004			
		FLEX005			
		FLEX006			
		FLEX007			
		FLEX007A			
		FLEX007B			
		FLEX011			
		FLEX021			
		FLEX022			
		FLEX023			
		FLEX024			
		FLEX028			
		FLEX033			
		FLEXSAMP			
		FT-12-197			
		FT-12-197-50			
		FT-12-250			
		FT-12-250-50			
		FT-12-276			
		FT-12-276-50			
		FT-12-375			
		FT-12-375-50			
		FT-12-440			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		FT-12-440-50 FT-12-500 FT-12-500-50 FT-18-197 FT-18-197-50 FT-18-250 FT-18-250-50 FT-18-276 FT-18-276-50 FT-18-375 FT-18-375-50 FT-18-440 FT-18-440-50 FT-18-500 FT-18-500-50 FT-24-197 FT-24-197-50 FT-24-250 FT-24-250-50 FT-24-276 FT-24-276-50 FT-24-375 FT-24-375-50 FT-24-440 FT-24-440-50 FT-24-500 FT-24-500-50 H-FLEX001 H-FLEX002 H-FLEX003 H-FLEX004 H-FLEX005 H-FLEX006 H-FLEX007 H-FLEX007A H-FLEX008H H-FLEX009 H-FLEX010 H-FLEX021 H-FLEX022 H-FLEX023 H-FLEX024 H-FLEX025 H-FLEX026 H-FLEX027 H-FLEX033 H-FLEX034 H-FLEX035 H-FLEXSAMP MED100.10 MED100.11 MED100.12 MED100.13 MED100.14 MED100.15 MED100.16 MED100.17 MED100.18 MED100.19 MED100.20 MED100.21			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		MED100.22			
		MED100.23			
		MED100.24			
		MED100.25			
		MED100.26			
		MED100.27			
		MED100.28			
		MED100.29			
		MED100.30			
		MED100.31			
		MED100.32			
		MED100.48			
		MED100.49			
		MED100.52			
		MED100.57			
		MED100.58			
		MED100.59			
		MED100.61			
		MED100.62			
		MJ-370			
		MJ-370C-1			
		PC-100C			
		PC-112C			
		PC-200C			
		PC-212C			
		PC-300P			
		PC-306P			
		PC-312P			
		PC-400P			
		PC-412P			
		PC-503			
		PC-512			
		PC-515			
		PP-16-039			
		PP-16-039-50			
		PP-16-062			
		PP-16-062-50			
		PP-16-087			
		PP-16-087-50			
		PP-16-105			
		PP-16-105-50			
		PP-16-125			
		PP-16-125-50			
		PP-16-158			
		PP-16-158-50			
		PP-18-197			
		PP-18-197-50			
		PP-18-250			
		PP-18-250-50			
		PP-18-393			
		PP-18-393-50			
		PP-18-591			
		PP-18-591-50			
		PP-18-750			
		PP-18-750-50			
		PP-22-039-50			
		PP-22-062-50			
		PP-22-087-50			
		PP-22-105-50			
		PP-22-125-50			
		PP-22-158-50			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		PP-22-197-50 PP-24-250-50 PT-28-118-50 PT-28-197-50 BR-06-039 PP-22-039 PP-22-062 PP-22-087 PP-22-105 PP-22-125 PP-22-158 PP-22-197 PP-24-250 PT-28-118 PT-28-197 FLEX008 FLEX009 FLEX025 FLEX026 BR-18-591 BR-18-880 BR-24-070 BR-24-080 BR-24-098 BR-24-197 BR-24-200 BR-24-236 BR-24-276 BR-24-312 BR-24-375 BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		96281.7 MED100.98 26474 26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197 BR-31-276 BR-3201 BR-3201-50 BR-4140			
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600			
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325			
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50 BR-075-24 BR-075-24-50 BR-075-32 BR-075-32-50 BR-075-42 BR-075-42-50 BR-075-99 BR-100-18 BR-100-18-50 BR-100-24 BR-100-24-50 BR-100-32 BR-100-32-50 BR-100-42 BR-100-42-50 BR-100-99, BR-150-18 BR-150-18-50 BR-150-24 BR-150-24-50 BR-150-32 BR-150-32-50 BR-150-42 BR-150-42-50 BR-150-99			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		BR-200-18 BR-200-18-50 BR-200-24 BR-200-24-50 BR-200-32 BR-200-32-50 BR-200-42 BR-200-42-50 BR-200-99 BR-3030 BR-3030-50 BR-3035 BR-3035-50 BR-3040 BR-3040-50 BR-3202 BR-3202-50 BR-3299 BR-3300 BR-3305 BR-3307 BR-3308 BR-3308-50 BR-3309 BR-3309-50 BR-3310 BR-3310-50 BR-3320 BR-3320-50 BR-3330 BR-3330-50 BR-3340 BR-3340-50 BR-3399 BR-3410 BR-3410-50 BR-3420 BR-3420-50 BR-3701 BR-3702 BR-3703 BR-3711-100 BR-3711-50 BR-3799-50 BR-3711			
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21-134 GMDN: 38835		
Irrigaticanules Beoogd doel: bedoeld voor gebruik bij wondirrigatie.	Key Surgical Cannulas (non-sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15-206 GMDN: 62389	084977100000000000000002M5	
	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06-01, 01800, 3-06-02, 13-06-02, 01801, 3-06-03, 13-06-03, 01802, 3-06-04, 13-06-04, 01803, 3-06-05, 13-06-			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
<p>Instrumentbeschermers</p> <p>Beoogd doel: Bedoeld om medische instrumenten af te dekken en te beschermen.</p>		<p>05, 01804, 3-06-07, I3-06-07, 01805, 3-11-01, I3-11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11-03, 01828, 3-11-04, I3-11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12-01, 01838, 3-12-02, I3-12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, I3-12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12-09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10-04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09-03, 01814, 3-09-04, I3-09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09-08, I3-09-08, 01472, 01473, 3-09-09, 01474, 01475, 01494, 3-09-10, 3-24-98, 3-24-99, 3-48-50, 3-80-03, 3-60-01, 3-60-02, 3-60-03, 3-60-04, 3-60-05, 3-60-06, 3-60-07, 3-60-08, 3-60-09, 3-60-10, 3-60-11, 01471, 01476, 01477, 01469, 01470, 01478, 01479, 01492, 01496, 01499, 3-01-01, 01865, 3-01-02, 01890, 3-01-03, 01866, 3-01-04, 01867, 3-01-05, 01891, 3-01-06, 01892, 3-02-01, 01876, 3-02-02, 3-02-</p>	<p>UMDNS: 16-222 GMDN: 63247</p>	<p>0849771000000000000003M7</p>	

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		03, 01877, 3-02-04, 01878, 3-02-06, 3-03-01, 01871, 3-03-02, 01872, 3-03-03, 01873, 3-03-04, 01874, 3-03-05, 01875, 3-03-06, 3-04-01, 01484, 3-04-02, 01485, 3-04-03, 01486, 3-04-04, 01487, 3-04-05, 01488, 3-04-06, 01489, 3-08-01, 01460, 3-08-02, 01461, 3-08-03, 01462, 3-08-04, 01463, 3-08-05, 01464, 3-08-06, 01465, 3-09-01, 3-09-02S, 3-15-01, 01868, 3-15-02, 01869, 3-15-03, 01870, 3-15-04, 01884, 3-15-05, 01885, 3-15-06, 01886, 3-21-03, 3-24-06, 3-24-20, , 3-42-95, 3-44-01, 3-44-02, 3-44-03, 3-44-04, 3-44-05, 3-44-06, 3-44-96, 3-44-97, 3-48-01,, 3-48-02, 3-48-03, 3-48-04, 3-48-05, 3-48-06, ,3-48-61, 3-48-62, 3-48-94, 3-48-95, 3-74-05, 3-74-06, I3-03-01, I3-03-02, I3-03-03, I3-04-01, I3-04-02, I3-04-03, I3-04-04, I3-04-05, I3-04-06, I3-08-01, I3-08-02, I3-08-03, I3-08-04, I3-08-05, I3-08-06, 3-03-11, 3-03-12, 3-03-13, 3-03-15, 3-04-11, 01806, 3-04-12, 01807, 3-04-13, 01808, 01809, 3-04-17, 01811, 3-04-18, 01812, 3-04-19, 01813, 3-08-11, 3-08-12, 3-08-13, 3-08-15, 3-08-17, 3-08-18, 3-08-19, 3-24-11, 3-24-13, 3-24-15, 3-24-17, 3-44-11, 3-44-12, 3-44-13, 3-44-15, 3-44-16, 3-44-17, 3-44-18, 3-44-19, 3-48-11, 3-48-12, 3-48-13, 3-48-15, 3-48-16,3-48-17, 3-48-18, 3-48-19, 3-74-11, 3-74-15, 3-78-			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
K-draad en pindoppen Beoogd doel: De K-draden en pinnen beschermen en afdekken.		11, I3-04-11, I3-04-12, I3-04-13, I3-04-15, I3-04-18, 3-04-07, 01480, 3-04-08, 01481, 3-04-09, 01482, 01810, 3-08-07, 01466, 3-08-08, 01467, 3-08-09, 01468, 3-15-07, 01887, 3-15-08, 01888, 3-15-09, 01889, 3-24-08, 3-24-09, 3-44-07, 3-44-08, 3-44-09, 3-48-07, 3-48-08, 3-48-09, 3-74-07, 3-74-09, I3-04-07, I3-04-08, I3-04-09, I3-08-07, I3-08-08, I3-08-09, 3-01-07, 3-01-08, 01824, 3-01-09, 3-02-07, 01879, 3-02-08, 3-02-09, 3-03-07, 3-03-08, 3-03-09, 3-16-05, 3-16-06, 3-16-07, 3-16-08, 01821, 3-16-09, 30000, 30001, 30002, 30003, 30004, 30005, 30006, 30007, 30008, 30009, 30010, 30012, 30013, 30014, 30015, 30016, 30017, 01850, 01851, 01852, 01853, 01854, TP-09-11, TP-09-12, TP-09-13, 3-02-05, 3-04-15, 3-06-50, 3-08-09, 3-08-100, 3-11-01, 01826			
	Key Surgical Instrument Tip Protectors	PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		01455 01457			
	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS			
Instrumentsterilisatietray	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS:12-143 GMDN:13730	084977100000000000000004M9	
	Key Surgical Finger Mat	FM-1810			
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50 DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806			
Beoogd doel: Bescherming van hulpmiddelen bij reiniging, sterilisatie en opslag.					

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		08940 08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Hoekbescherming voor tray Beoogd doel: beschermen van de hoeken van de sterilisatietray en de sterilisatiewikkel	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15-907 GMDN: 63494 & 65133	08497710000000000000005MB	
Lijmrestenverwijderaar Beoogd doel: oplossing voor verwijdering van lijmresten uit medische instrumenten	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN: 64150	08497710000000000000006MD	
Heteluchtfolie Beoogd doel: bedoeld voor gebruik in sterilisatiemethoden met warme lucht	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735	08497710000000000000007MF	
Sterilisatiedoeken Beoogd doel: steriele barrièrewikkel	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100 CB/TWO120 CB/TWR120 CB/TWRAP060 CB/TWRAP075 CB/TWRAP090 CB/TWRAP100 CB/TWRAP1012 CB/TWRAP120 CB/TWRAP1315 CB/TWRAP1315X CB/TWRAP150 CB/TWRAP150F3W CB/TWRAP18135	UMDNS: GMDN: 13735	08497710000000000000008MH	

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CB/TWRAP1815 CB/TWRAP5075 CB/TWRAPDRY050 CB/TWRAPDRY060 CB/TWRAPDRY075 CB/TWRAPDRY090 CB/TWRAPDRY100 CB/TWRAPDRY120 CB/TWRAPDRY1315X CB/TWRAPDRY140 CB/TWY100 CB/TWY120 CB030 CB050 CB060 CB075 CB090 CB100 CB100DB CB1012 CB1014 CB120 CB120DB CB1315 CB1315DB CB140 CB150 CB1540 CB1715 CB1715DB CB1815 CB1815DB CBA/TWRAP120 CBA/TWRAP140 CBA050 CBA075 CBA090 CBA100 CBA120 CBA1415 CBU/TWRAP100 CBU/TWRAP1215 CBU/TWRAP1315 CBU/TWY120 CBU1014 CBU1014DB CBU120 CBU1315 CBU150 CDB/CG060 CDB/CG075 CDB/CG075DB CDB/CG090 CDB/CG100 CDB/CG1012 CDB/CG1012DB CDB/CG1014 CDB/CG120 CDB/CG120DB CDB/CG1215 CDB/CG1215DB			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CDB/CG1315 CDB/CG1315DB CDB/CG140 CDB/CG150 CDB/CG150DB CDB/CG1815 CDB/CG1815DB CDB/GC120 CDB/GC140 CDB/TWO090 CDB/TWR120 CDB/TWRAP090 CDB/TWRAP100 CDB140 CDB1815 CDB5075 CDG/CB060 CDG/CB075 CDG/CB075DB CDG/CB090 CDG/CB100 CDG/CB1012DB CDG/CB1015 CDG/CB120 CDG/CB120DB CDG/CB1215DB CDG/CB1315 CDG/CB1315DB CDG/CB1815DB CDG/TWO1215 CDG/TWO1315X CDG/TWRAP060 CDG/TWRAP075 CDG/TWRAP090 CDG/TWRAP100 CDG/TWRAP100DB CDG/TWRAP1014 CDG/TWRAP120 CDG/TWRAP120DB CDG/TWRAP1214 CDG/TWRAP1215 CDG/TWRAP1315 CDG/TWRAP150 CDG/TWY1315 CDG075 CDG090 CDG100 CDG120 CDG1215 CDG140 CDG150 CDG1815 CG/CB050 CG/CB060 CG/CB075 CG/CB075DB CG/CB090 CG/CB100 CG/CB100DB CG/CB1012 CG/CB1014			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CG/CB1014DB CG/CB1075 CG/CB1075DB CG/CB1090 CG/CB120 CG/CB1215 CG/CB1215X CG/CB1315 CG/CB1315/P120 CG/CB1315DB CG/CB1315X CG/CB140 CG/CB140X CG/CB150 CG/CB1715 CG/CB1715/F4 CG/CB1815 CG/CB1815/P72 CG/CB5045 CG/CBA120 CG/CBU075 CG/CBU090 CG/CBU100 CG/CBU100DB CG/CBU1012 CG/CBU1014 CG/CBU1090 CG/CBU1215 CG/CBU1315DB CG/CBU1315X CG/PRO1215 CG/PRO1815 CG/TWO060 CG/TWO090 CG/TWO1012 CG/TWO1012DB CG/TWO1014 CG/TWO1014DB CG/TWO1075 CG/TWO1075DB CG/TWO1090DB CG/TWO120 CG/TWO1215 CG/TWO1215DB CG/TWO1215PZDB CG/TWO1315 CG/TWO140 CG/TWO1715 CG/TWO1715DB CG/TWO1815 CG/TWO1815DB CG/TWR060 CG/TWR090DB CG/TWR100 CG/TWR100DB CG/TWR1014 CG/TWR1090DB CG/TWR1215PZDB CG/TWR1315 CG/TWR1315PZDB CG/TWR1715DB			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CG/TWR1815PZDB CG/TWRAP060 CG/TWRAP075 CG/TWRAP075DB CG/TWRAP090 CG/TWRAP090DB CG/TWRAP100 CG/TWRAP100DB CG/TWRAP1012 CG/TWRAP1012DB CG/TWRAP1014 CG/TWRAP1014DB CG/TWRAP1075 CG/TWRAP1090 CG/TWRAP1090DB CG/TWRAP120 CG/TWRAP120DB CG/TWRAP1215 CG/TWRAP1215DB CG/TWRAP1215PZDB CG/TWRAP1315 CG/TWRAP1315DB CG/TWRAP1315PZ CG/TWRAP1315PZDB CG/TWRAP140 CG/TWRAP140DB CG/TWRAP150 CG/TWRAP1715DB CG/TWRAP1815 CG/TWRAP1815/F4 CG/TWRAP1815DB CG/TWRAP5075 CG/TWRAP5075DB CG/TWRAPDRY060DB CG/TWRAPDRY075 CG/TWRAPDRY090 CG/TWRAPDRY090DB CG/TWRAPDRY100 CG/TWRAPDRY1012 CG/TWRAPDRY1014 CG/TWRAPDRY1075 CG/TWRAPDRY1090 CG/TWRAPDRY120 CG/TWRAPDRY120DB CG/TWRAPDRY1215 CG/TWRAPDRY1315 CG/TWRAPDRY1315D CG/TWRAPDRY1315X CG/TWRAPDRY140 CG/TWRAPDRY150 CG/TWRAPDRY1715 CG/TWRAPDRY1815 CG/TWRAPDRY1815M CG/TWY060 CG/TWY075DB CG/TWY090 CG/TWY090DB CG/TWY100 CG/TWY100DB CG/TWY1012 CG/TWY1012DB			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CG/TWY1090 CG/TWY1090DB CG/TWY1215 CG/TWY1215PZDB CG/TWY1315 CG/TWY1315DB CG/TWY1815 CG/WB120 CG/WB1315 CG/WB1815 CG060 CG075 CG075DB CG090 CG090/P150 CG100 CG100/P150 CG100DB CG120 CG120DB CG1215 CG1315 CG140 CG150 CG1715DB CG1815DB CG5075 CGP/CB100 CGP/CB120 CGP/CB1715 CGP/CB1815 CGP/CBU100 CGP/CBU1014 CGP/CBU1014DB CGP/CBU1090 CGP/CBU1215 CGP/CBU1315 CGP/CBU140 CGP/CBU1815 CGP/TWO100 CGP/TWO1012 CGP/TWO1215 CGP/TWO1815 CGP/TWRAP060 CGP/TWRAP060DB CGP/TWRAP075 CGP/TWRAP075DB CGP/TWRAP090 CGP/TWRAP100 CGP/TWRAP1012 CGP/TWRAP1075 CGP/TWRAP120 CGP/TWRAP1215 CGP/TWRAP1315 CGP/TWRAP150 CGP/TWRAP1815 CGP/TWY075 CGP/TWY100 CGP/TWY1315 CGP/TWY1815 CGP1315			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CGP150 CGX/CB075 CGX/CB075DB CGX/CB090 CGX/CB100 CGX/CB100DB CGX/CB1012 CGX/CB1012DB CGX/CB1014 CGX/CB1090 CGX/CB1090DB CGX/CB1215 CGX/CB1215DB CGX/CB1315 CGX/CB1315/P120 CGX/CB1315P120DB CGX/CB1715 CGX/CB1715DB CGX/CB1815 CGX/CB1815DB CGX/CB5075 CGX/CB5075DB CGX/CBU060 CGX/CBU060DB CGX/CBU100 CGX/CBU1012 CGX/CBU1014 CGX/CBU1014DB CGX/CBU1090 CGX/CBU1090DB CGX/CBU1215 CGX/CBU1315 CGX/CBU1315DB CGX/CBU1815 CGX/TWO1012DB CGX/TWO1090DB CGX/TWO1215PZDB CGX/TWO1315 CGX/TWR1090DB CGX/TWR1215PZDB CGX/TWR1715DB CGX/TWRAP075DB CGX/TWRAP090 CGX/TWRAP090DB CGX/TWRAP100 CGX/TWRAP100DB CGX/TWRAP1012 CGX/TWRAP1012DB CGX/TWRAP1090DB CGX/TWRAP1215 CGX/TWRAP1215PZDB CGX/TWRAP1315 CGX/TWRAP1315PZDB CGX/TWRAP1715DB CGX/TWRAP1815 CGX/TWRAP1815DB CGX/TWRAP5075 CGX/TWRAP5075DB CGX/TWRAPD100DB CGX/TWRAPD1215DB CGX/TWRAPD1315DB			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CGX/TWRAPDRY100 CGX/TWRAPDRY1215 CGX/TWRAPDRY1315 CGX/TWY090DB CGX/TWY1012DB CGX/TWY1090DB CGX/TWY1215PZDB CGX/TWY1315 CGX/TWY1315DB CGX090 CGX100 CGX100DB CGX120 CGX1715DB REL340G/CBU100 REL340G/CBU1014 REL340G/CBU1215 REL340G/CBU1315 RELGRN/CB100 RELGRN/CB1050 RELGRN/CB1315 RELGRN/CB140 RELGRN/WB1815 WB/TDRY100DB WB/TWO075 WB/TWO1012 WB/TWO1014 WB/TWO1014DB WB/TWO1315 WB/TWRAP060 WB/TWRAP075 WB/TWRAP090 WB/TWRAP100 WB/TWRAP100DB WB/TWRAP1012 WB/TWRAP1014DB WB/TWRAP1075 WB/TWRAP1215 WB/TWRAP1215DB WB/TWRAP1315 WB/TWRAP1815 WB/TWRAPDRY060 WB/TWRAPDRY090 WB/TWRAPDRY100 WB/TWRAPDRY120 WB/TWRAPDRY1315X WB/TWRAPDRY150 WB/TWRAPDRY150F3 WB/TWY090 WB/TWY1014 WB/TWY1215 WB075 WB090 WB100 WB1014 WB120 WB140 CBA060 CBU140 CDG1315 CG/TWRAPDRY060			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		CGX/TWY1215 WB/TWRAPDRY1012 MC-CBA/TWRAP090 MC-CBA/TWRAP100 MC-CBA/TWRAP120 RELGRN/CBU100 RELGRN/CBU140 CG/CBU120 CGX/TWY090 CGX/TWY1012 CG/CBU1815 CB/TDRY075 CB/TDRY090 CB/TDRY100 CB/TDRY060 CB/TDRY120 CGX/TWR1815			
Transportdoek Beoogd doel: transportbarrièrewikkel	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB	GMDN: 13735	0849771000000000000009MK	

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB TWRAP1014 TWRAP1090DB TWRAP120 TWRAP1215 TWRAP1215DB TWRAP1315 TWRAP1315DB TWRAP140 TWRAP140DB TWRAP150 TWRAP150DB TWRAP1715 TWRAP1715DB TWRAP1815 TWRAP1815DB TWRAP5090 TWRAP5390 TWRAP7537 TWRAP75375 TWRAPDRY050 TWRAPDRY060 TWRAPDRY075 TWRAPDRY090 TWRAPDRY100 TWRAPDRY1012 TWRAPDRY1014 TWRAPDRY120 TWRAPDRY1315 TWRAPDRY140 TWRAPDRY1815 TWRAPDRY3015 TWRAPDRY3015SGL TWRAPDRY5075 TWRAPDRY7560 TWRAPDRYOFFCUT TWY075 TWY075DB TWY090 TWY100 TWY100DB TWY1012 TWY1014 TWY120 TWY1215			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		TWY1215DB TWY1315 TWY1315DB TWY140 TWY1715 TWY1715DB TWY1815 CDBAG002G H-THCOVER001 H-THCOVER002 H-THCOVER003 H-THOCOVER001 H-THOCOVER002 H-THOCOVER003 H-THRCOVER001 H-THRCOVER002 H-THRCOVER003 H-THYCOVER001 H-THYCOVER002 H-THYCOVER003 PC000700 PC000800 PC000900 PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Transportdoek Beoogd doel: transportbarrièrewikkel	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011	GMDN: 13735		

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400			
Containerfilters Beoogd doel: voor gebruik met sterilisatiecontainers.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157 01158 01167 01168 01181 01183 01186 01188 01189 01194 01196 01198 01300 01304 01306 01312 01314 01315 01317 01318 01319 01321 01322 01323 01327 01330 01331 01332 01346 01347 01348 01350 01355 01356 01363 01365	GMDN: 60909	0849771000000000000010M4	

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		01366 01367 01368 01369 01373 04111 1070020 26510 27320 27330 27340 27350 27360 55-291-01-04 61140 71140 71141 71194 91140 26515 27325 27335 27345 27355 27365 91140 26510 ME01194 ME26515 ME27325 ME27335 ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Tray liners Beoogd doel: voor gebruik bij sterilisatie van medische hulpmiddelen.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007 H-TLC008	GMDN: 60908	0849771000000000000011M6	

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		H-TLC009			
		H-TLC010			
		H-TLC011			
		H-TLC012			
		H-TLC013			
		H-TLC078			
		H-TLC109			
		H-TLC110			
		H-TLC111			
		H-TLC119			
		H-TLC213			
		H-TLC214			
		H-TLC215			
		LIB1328			
		LIB250X320			
		LIB300X360			
		LIB300X500			
		LIB3025			
		LIB3050			
		LIB400X500			
		LINH3020			
		LINH3041			
		LINH4555			
		MILB002			
		MILB003			
		MILB004			
		MILB005			
		MILB006			
		MILB007			
		MILB008			
		MILB009			
		MILB011			
		MILB012			
		MILB016			
		MILB017			
		MILB019			
		MILB020			
		MILB021			
		MILB022			
		MILB025			
		MILB027			
		MILB029			
		MILB056			
		MILB120X250			
		MILB130X230			
		MILB170X270			
		MILB250X300			
		MILB300X400			
		MILB305X450			
		MILB350x450			
		MILB375X600			
		MILB450X650			
		MILB500X900			
		PC002100			
		PC002200			
		PC008800			
		PC008900			
		PC009000			
		PC009100			
		PC009200			
		PC009400			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		PC009800			
		PC009900			
		PC010000			
		PC010200			
		PC010400			
		PC010700			
		PC010800			
		PC011200			
		PC011300			
		PC011400			
		PC011700			
		PC011800			
		PC013300			
		PC013600			
		TL-101-200			
		TL-202-500			
		TL-203-500			
		TL-204-500			
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		TLC052			
		TLC055			
		TLC060			
		TLC066			
		TLC069			
		TLC071			
		TLC072			
		TLC078			
		TLC079			
		TLC081			
		TLC085			
		TLC086			
		TLC087			
		TLC095			
		TLC096			

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300 PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545	GMDN: 61664		

Productfamilie	Producthandelsnaam	Item Number	Productcode (s)	Basis UDI-DI	Algemene specificaties
		SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Onderhoudsolie Beoogd doel: bedoeld om medische hulpmiddelen te smeren.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	0849771000000000000012M8	
Chiol Ultra Beoogd doel: reinigungsoplossing voor het verwijderen van vuil van metalen oppervlakken.	Chiol Ultra	02110	GMDN: 63385	0849771000000000000013MA	

Wij benoemen hierbij Medical Device Safety Service (MDSS)
Schiffgraben 41
D-30175 Hannover
Duitsland

als Europese gemachtigde vertegenwoordiger zoals gedefinieerd in artikel 2 (32) van de MDR.

Conformiteitsbeoordelingsroute: bijlage IV

Afgegeven door:

Handtekening:



Datum: 2021-12-28

Naam: Coletta Cohara
Functie: Directeur Kwaliteit en regelgevingshandhaving
Plaats van afgifte van DoC: Key Surgical LLC
8101 Wallace RD.
Eden Prairie, Min 55344
USA

Nós, o fabricante,

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

garantimos e declaramos com responsabilidade exclusiva, que os seguintes dispositivos médicos da Classe I não esterilizados (de acordo com o RDM), não reutilizáveis e não mensuráveis cumprem as disposições do Anexo IV do Regulamento (UE) relativo aos dispositivos médicos (RDM), que lhes são aplicáveis. Estes dispositivos estão em conformidade com o Regulamento 2017/745 relativo aos dispositivos médicos que prevê a emissão da declaração UE de conformidade. Toda a documentação de apoio é mantida nas instalações do fabricante.

Família de produtos	Nome comercial do produto	Item Number	Código(s) do(s) produto(s)	UDI-DI básico	Especificações comuns
Escovas de limpeza	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	0849771000000000000001M3	Não existem especificações comuns estabelecidas pela Comissão Europeia ao abrigo do RDM que se apliquem ao produto da Key Surgical nesta declaração. As normas reconhecidas aplicadas são identificadas na documentação técnica.
	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336	UMDNS: 21-134 GMDN: 34878 e 38835		

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AT-18-105
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BZ-24-125-50
FLEX001
FLEX002
FLEX003
FLEX004
FLEX005
FLEX006
FLEX007
FLEX007A
FLEX007B
FLEX011
FLEX021
FLEX022
FLEX023
FLEX024
FLEX028
FLEX033
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H-FLEX007
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H-FLEX023
H-FLEX024
H-FLEX025
H-FLEX026
H-FLEX027
H-FLEX033
H-FLEX034
H-FLEX035
H-FLEXSAMP
MED100.10
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MED100.62
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MJ-370C-1
PC-100C
PC-112C
PC-200C

PC-212C
PC-300P
PC-306P
PC-312P
PC-400P
PC-412P
PC-503
PC-512
PC-515
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PP-16-062
PP-16-062-50
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PP-16-158
PP-16-158-50
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PP-18-197-50
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PP-18-591
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PP-18-750
PP-18-750-50
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PP-22-062-50
PP-22-087-50
PP-22-105-50
PP-22-125-50
PP-22-158-50
PP-22-197-50
PP-24-250-50
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PT-28-197-50
BR-06-039
PP-22-039
PP-22-062
PP-22-087
PP-22-105
PP-22-125
PP-22-158
PP-22-197
PP-24-250
PT-28-118
PT-28-197
FLEX008
FLEX009
FLEX025
FLEX026
BR-18-591
BR-18-880
BR-24-070
BR-24-080
BR-24-098
BR-24-197
BR-24-200
BR-24-236
BR-24-276

		BR-24-312 BR-24-375 BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4 96281.7 MED100.98 26474 26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118			

		BR-31-197 BR-31-276 BR-3201 BR-3201-50 BR-4140			
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600			
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325			
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50			

BR-075-24
BR-075-24-50
BR-075-32
BR-075-32-50
BR-075-42
BR-075-42-50
BR-075-99
BR-100-18
BR-100-18-50
BR-100-24
BR-100-24-50
BR-100-32
BR-100-32-50
BR-100-42
BR-100-42-50
BR-100-99,
BR-150-18
BR-150-18-50
BR-150-24
BR-150-24-50
BR-150-32
BR-150-32-50
BR-150-42
BR-150-42-50
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BR-200-24-50
BR-200-32
BR-200-32-50
BR-200-42
BR-200-42-50
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BR-3305
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BR-3320
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BR-3330
BR-3330-50
BR-3340
BR-3340-50
BR-3399
BR-3410
BR-3410-50
BR-3420
BR-3420-50
BR-3701
BR-3702

		BR-3703 BR-3711-100 BR-3711-50 BR-3799-50 BR-3711		
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21- 134 GMDN: 38835	
Cânulas de irrigação Finalidade pretendida: destina-se a utilização na irrigação de feridas.	Key Surgical Cannulas (non- sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15- 206 GMDN: 62389	0849771000000000000002M5
Protetores de instrumentos Finalidade pretendida: destinam-se a cobrir e proteger os instrumentos médicos.	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3-06- 01, 01800, 3-06-02, I3- 06-02, 01801, 3-06-03, I3-06-03, 01802, 3-06- 04, I3-06-04, 01803, 3- 06-05, I3-06-05, 01804, 3-06-07, I3-06- 07, 01805, 3-11-01, I3- 11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11- 03, 01828, 3-11-04, I3- 11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11- 06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12- 01, 01838, 3-12-02, I3- 12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12- 06, 01843, 3-12-07, I3- 12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12- 09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14- 07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10-02,3-10-03, 3-10- 04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3- 04-98, 3-04-99, 3-05- 02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05- 24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09- 03, 01814, 3-09-04, I3- 09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09- 08, I3-09-08, 01472, 01473, 3-09-09, 01474,	UMDNS: 16- 222 GMDN: 63247	0849771000000000000003M7

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01469, 01470, 01478,
01479, 01492, 01496,
01499, 3-01-01, 01865,
3-01-02, 01890, 3-01-
03, 01866, 3-01-04,
01867, 3-01-05, 01891,
3-01-06, 01892, 3-02-
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01872, 3-03-03, 01873,
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01485, 3-04-03, 01486,
3-04-04, 01487, 3-04-
05, 01488, 3-04-06,
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01885, 3-15-06, 01886,
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3-44-96, 3-44-97, 3-48-
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3-48-94, 3-48-95, 3-74-
05, 3-74-06, I3-03-01,
I3-03-02, I3-03-03, I3-
04-01, I3-04-02, I3-04-
03, I3-04-04, I3-04-05,
I3-04-06, I3-08-01, I3-
08-02, I3-08-03, I3-08-
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	<p>Key Surgical Instrument Tip Protectors</p>	<p>PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C</p>			

Tampas para fios K e pinos Finalidade pretendida: proteger e cobrir os fios K e pinos.		01455 01457		
	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS		
Tabuleiro de esterilização de instrumentos Finalidade pretendida: proteção de dispositivos na limpeza, esterilização e armazenamento.	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS: 12-143 GMDN: 13730	0849771000000000000004M9
	Key Surgical Finger Mat	FM-1810		
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50 DIV116		

		DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Protetores de cantos Key Surgical Finalidade pretendida: proteger os cantos dos tabuleiros de esterilização e o invólucro de esterilização	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15-907 GMDN: 63494 & 65133	084977100000000000000005MB	
Removedor de adesivo Finalidade pretendida: solução para remoção de resíduos adesivos de instrumentos médicos	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN: 64150	084977100000000000000006MD	
Película de ar quente Finalidade pretendida: destina-se a utilização em métodos de esterilização com ar quente	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735	084977100000000000000007MF	
Invólucro de esterilização Finalidade pretendida:	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060	UMDNS: GMDN: 13735	084977100000000000000008MH	

invólucro de
barreira
esterilizado

CB/TWO075
CB/TWO090
CB/TWO100
CB/TWO120
CB/TWR120
CB/TWRAP060
CB/TWRAP075
CB/TWRAP090
CB/TWRAP100
CB/TWRAP1012
CB/TWRAP120
CB/TWRAP1315
CB/TWRAP1315X
CB/TWRAP150
CB/TWRAP150F3W
CB/TWRAP18135
CB/TWRAP1815
CB/TWRAP5075
CB/TWRAPDRY050
CB/TWRAPDRY060
CB/TWRAPDRY075
CB/TWRAPDRY090
CB/TWRAPDRY100
CB/TWRAPDRY120
CB/TWRAPDRY1315X
CB/TWRAPDRY140
CB/TWY100
CB/TWY120
CB030
CB050
CB060
CB075
CB090
CB100
CB100DB
CB1012
CB1014
CB120
CB120DB
CB1315
CB1315DB
CB140
CB150
CB1540
CB1715
CB1715DB
CB1815
CB1815DB
CBA/TWRAP120
CBA/TWRAP140
CBA050
CBA075
CBA090
CBA100
CBA120
CBA1415
CBU/TWRAP100
CBU/TWRAP1215
CBU/TWRAP1315
CBU/TWY120
CBU1014
CBU1014DB
CBU120
CBU1315
CBU150

CDB/CG060
CDB/CG075
CDB/CG075DB
CDB/CG090
CDB/CG100
CDB/CG1012
CDB/CG1012DB
CDB/CG1014
CDB/CG120
CDB/CG120DB
CDB/CG1215
CDB/CG1215DB
CDB/CG1315
CDB/CG1315DB
CDB/CG140
CDB/CG150
CDB/CG150DB
CDB/CG1815
CDB/CG1815DB
CDB/GC120
CDB/GC140
CDB/TWO090
CDB/TWR120
CDB/TWRAP090
CDB/TWRAP100
CDB140
CDB1815
CDB5075
CDG/CB060
CDG/CB075
CDG/CB075DB
CDG/CB090
CDG/CB100
CDG/CB1012DB
CDG/CB1015
CDG/CB120
CDG/CB120DB
CDG/CB1215DB
CDG/CB1315
CDG/CB1315DB
CDG/CB1815DB
CDG/TWO1215
CDG/TWO1315X
CDG/TWRAP060
CDG/TWRAP075
CDG/TWRAP090
CDG/TWRAP100
CDG/TWRAP100DB
CDG/TWRAP1014
CDG/TWRAP120
CDG/TWRAP120DB
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CDG/TWRAP1215
CDG/TWRAP1315
CDG/TWRAP150
CDG/TWY1315
CDG075
CDG090
CDG100
CDG120
CDG1215
CDG140
CDG150
CDG1815
CG/CB050

CG/CB060
CG/CB075
CG/CB075DB
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CG/CB5045
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CG/PRO1215
CG/PRO1815
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CG/TWR090DB
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CG/TWY1215PZDB
CG/TWY1315
CG/TWY1315DB
CG/TWY1815
CG/WB120
CG/WB1315
CG/WB1815
CG060
CG075
CG075DB
CG090
CG090/P150
CG100
CG100/P150
CG100DB
CG120
CG120DB
CG1215
CG1315
CG140
CG150
CG1715DB
CG1815DB
CG5075
CGP/CB100
CGP/CB120
CGP/CB1715
CGP/CB1815
CGP/CBU100
CGP/CBU1014
CGP/CBU1014DB
CGP/CBU1090
CGP/CBU1215
CGP/CBU1315
CGP/CBU140
CGP/CBU1815
CGP/TWO100
CGP/TWO1012
CGP/TWO1215
CGP/TWO1815
CGP/TWRAP060
CGP/TWRAP060DB
CGP/TWRAP075
CGP/TWRAP075DB
CGP/TWRAP090
CGP/TWRAP100
CGP/TWRAP1012
CGP/TWRAP1075
CGP/TWRAP120
CGP/TWRAP1215
CGP/TWRAP1315
CGP/TWRAP150
CGP/TWRAP1815
CGP/TWY075
CGP/TWY100
CGP/TWY1315
CGP/TWY1815
CGP1315
CGP150
CGX/CB075
CGX/CB075DB
CGX/CB090

CGX/CB100
CGX/CB100DB
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CGX/CB1012DB
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CGX/TWR1090DB
CGX/TWR1215PZDB
CGX/TWR1715DB
CGX/TWRAP075DB
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CGX/TWRAP1215PZDB
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CGX/TWRAP1715DB
CGX/TWRAP1815
CGX/TWRAP1815DB
CGX/TWRAP5075
CGX/TWRAP5075DB
CGX/TWRAPD100DB
CGX/TWRAPD1215DB
CGX/TWRAPD1315DB
CGX/TWRAPDRY100
CGX/TWRAPDRY1215
CGX/TWRAPDRY1315
CGX/TWY090DB
CGX/TWY1012DB
CGX/TWY1090DB
CGX/TWY1215PZDB
CGX/TWY1315

CGX/TWY1315DB
CGX090
CGX100
CGX100DB
CGX120
CGX1715DB
REL340G/CBU100
REL340G/CBU1014
REL340G/CBU1215
REL340G/CBU1315
RELGRN/CB100
RELGRN/CB1050
RELGRN/CB1315
RELGRN/CB140
RELGRN/WB1815
WB/TDRY100DB
WB/TWO075
WB/TWO1012
WB/TWO1014
WB/TWO1014DB
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WB/TWRAP075
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WB/TWRAP100DB
WB/TWRAP1012
WB/TWRAP1014DB
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WB/TWRAP1815
WB/TWRAPDRY060
WB/TWRAPDRY090
WB/TWRAPDRY100
WB/TWRAPDRY120
WB/TWRAPDRY1315X
WB/TWRAPDRY150
WB/TWRAPDRY150F3
WB/TWY090
WB/TWY1014
WB/TWY1215
WB075
WB090
WB100
WB1014
WB120
WB140
CBA060
CBU140
CDG1315
CG/TWRAPDRY060
CGX/TWY1215
WB/TWRAPDRY1012
MC-CBA/TWRAP090
MC-CBA/TWRAP100
MC-CBA/TWRAP120
RELGRN/CBU100
RELGRN/CBU140
CG/CBU120
CGX/TWY090
CGX/TWY1012
CG/CBU1815
CB/TDRY075

		CB/TDRY090 CB/TDRY100 CB/TDRY060 CB/TDRY120 CGX/TWR1815			
Invólucro de transporte Finalidade pretendida: invólucro de barreira de transporte	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012	GMDN: 13735	0849771000000000000009MK	

TWRAP1012DB
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TWRAP1090DB
TWRAP120
TWRAP1215
TWRAP1215DB
TWRAP1315
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TWRAP140
TWRAP140DB
TWRAP150
TWRAP150DB
TWRAP1715
TWRAP1715DB
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TWRAP1815DB
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TWRAP5390
TWRAP7537
TWRAP75375
TWRAPDRY050
TWRAPDRY060
TWRAPDRY075
TWRAPDRY090
TWRAPDRY100
TWRAPDRY1012
TWRAPDRY1014
TWRAPDRY120
TWRAPDRY1315
TWRAPDRY140
TWRAPDRY1815
TWRAPDRY3015
TWRAPDRY3015SGL
TWRAPDRY5075
TWRAPDRY7560
TWRAPDRYOFFCUT
TWY075
TWY075DB
TWY090
TWY100
TWY100DB
TWY1012
TWY1014
TWY120
TWY1215
TWY1215DB
TWY1315
TWY1315DB
TWY140
TWY1715
TWY1715DB
TWY1815
CDBAG002G
H-THCOVER001
H-THCOVER002
H-THCOVER003
H-THCOVER001
H-THCOVER002
H-THCOVER003
H-THRCOVER001
H-THRCOVER002
H-THRCOVER003
H-THYCOVER001
H-THYCOVER002
H-THYCOVER003

		PC000700 PC000800 PC000900 PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELLO01 TCOVER-YELLO02 TCOVER-YELLO03			
Invólucro de transporte Finalidade pretendida: invólucro de barreira de transporte	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN: 13735		
Filtros para recipientes Finalidade pretendida: para utilização com recipientes de esterilização.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152	GMDN: 60909	0849771000000000000010M4	

01153
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01373
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1070020
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27330
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27360
55-291-01-04
61140
71140
71141
71194
91140
26515
27325
27335
27345
27355
27365
91140
26510
ME01194

		ME26515 ME27325 ME27335 ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Forros de tabuleiros Finalidade pretendida: para utilização na esterilização de dispositivos médicos.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007 H-TLC008 H-TLC009 H-TLC010 H-TLC011 H-TLC012 H-TLC013 H-TLC078 H-TLC109 H-TLC110 H-TLC111 H-TLC119 H-TLC213 H-TLC214 H-TLC215 LIB1328 LIB250X320 LIB300X360 LIB300X500 LIB3025 LIB3050 LIB400X500 LINH3020 LINH3041 LINH4555 MILB002 MILB003 MILB004 MILB005 MILB006 MILB007 MILB008 MILB009 MILB011	GMDN: 60908	0849771000000000000011M6	

MILB012
MILB016
MILB017
MILB019
MILB020
MILB021
MILB022
MILB025
MILB027
MILB029
MILB056
MILB120X250
MILB130X230
MILB170X270
MILB250X300
MILB300X400
MILB305X450
MILB350x450
MILB375X600
MILB450X650
MILB500X900
PC002100
PC002200
PC008800
PC008900
PC009000
PC009100
PC009200
PC009400
PC009800
PC009900
PC010000
PC010200
PC010400
PC010700
PC010800
PC011200
PC011300
PC011400
PC011700
PC011800
PC013300
PC013600
TL-101-200
TL-202-500
TL-203-500
TL-204-500
TLC001
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		TLC023 TLC024 TLC027 TLC029R TLC030 TLC031 TLC034 TLC036 TLC045 TLC051 TLC052 TLC055 TLC060 TLC066 TLC069 TLC071 TLC072 TLC078 TLC079 TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200	GMDN: 61664		

		PC012300 PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Óleo de manutenção Finalidade pretendida: destina-se a utilização na lubrificação de dispositivos médicos.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	0849771000000000000012M8	
Chirol Ultra Finalidade pretendida: solução de limpeza para remoção de sujidades de superfícies metálicas.	Chirol Ultra	02110	GMDN: 63385	0849771000000000000013MA	

Pela presente, nomeamos Medical Device Safety Service (MDSS)
Schiffgraben 41
D-30175 Hannover
Alemanha

como a representante autorizada na Europa, conforme definido no artigo 2.º (32) do RDM.

Via de avaliação de conformidade: Anexo IV

Emitido por:

Assinatura:



Data: 2021-12-28

Nome:

Coletta Cohara

Cargo:

Diretor da Qualidade e Conformidade
Regulamentar

**Local de emissão
da DC:**

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

Üretici olarak biz,

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

aşağıdaki Sınıf I steril olmayan (MDR uyarınca), yeniden kullanılmayan, ölçüm niteliği taşımayan cihazların, bu cihazlar için geçerli olan 2017/745 sayılı AB Tıbbi Cihaz Regülasyonu (MDR) Tıbbi Cihazlara ilişkin Ek IV hükümlerini karşıladığını tüm sorumluluğu üstlenerek temin ve beyan ederiz. Bu cihazlar, AB uygunluk beyanının verilmesini düzenleyen 2017/745 sayılı Tıbbi Cihaz Regülasyonuna uygundur. Destekleyici belgelerin tamamı üreticinin tesislerinde saklanır.

Ürün Ailesi	Ürün Ticari Adı	Item Number	Ürün Kodları	Temel UDI-DI	Genel Spesifikasyonlar
Temizlik Fırçaları	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	0849771000000000000000001M3	MDR kapsamında Avrupa Komisyonu tarafından belirlenen ve bu Beyandaki Key Surgical ürünleri için geçerli olan genel spesifikasyon yoktur. Tanınan geçerli standartlar, teknik belgelerde belirtilmiştir.
	Hedeflenen Amaç: Tıbbi cihazların temizlenmesi	Key Surgical Instrument and Channel Cleaning Brushes	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336 09338 09339		

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PC-200C
PC-212C
PC-300P

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PC-400P
PC-412P
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BR-24-312
BR-24-375

		BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4 96281.7 MED100.98 26474 26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197 BR-31-276			

		BR-3201 BR-3201-50 BR-4140			
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600			
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325			
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50 BR-075-24			

BR-075-24-50
BR-075-32
BR-075-32-50
BR-075-42
BR-075-42-50
BR-075-99
BR-100-18
BR-100-18-50
BR-100-24
BR-100-24-50
BR-100-32
BR-100-32-50
BR-100-42
BR-100-42-50
BR-100-99,
BR-150-18
BR-150-18-50
BR-150-24
BR-150-24-50
BR-150-32
BR-150-32-50
BR-150-42
BR-150-42-50
BR-150-99
BR-200-18
BR-200-18-50
BR-200-24
BR-200-24-50
BR-200-32
BR-200-32-50
BR-200-42
BR-200-42-50
BR-200-99
BR-3030
BR-3030-50
BR-3035
BR-3035-50
BR-3040
BR-3040-50
BR-3202
BR-3202-50
BR-3299
BR-3300
BR-3305
BR-3307
BR-3308
BR-3308-50
BR-3309
BR-3309-50
BR-3310
BR-3310-50
BR-3320
BR-3320-50
BR-3330
BR-3330-50
BR-3340
BR-3340-50
BR-3399
BR-3410
BR-3410-50
BR-3420
BR-3420-50
BR-3701
BR-3702
BR-3703

		BR-3711-100 BR-3711-50 BR-3799-50 BR-3711			
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21- 134 GMDN: 38835		
İrigasyon Kanülleri		05001, 05003, 05005, 05007, 05009	UMDNS: 15- 206 GMDN: 62389		0849771000000000000002M5
Hedeflenen Amaç: Yara irigasyonunda kullanılmak üzere tasarlanmıştır.	Key Surgical Cannulas (non- sterile)				
Alet Korumaları		3-48-32, 3-48-44, 3- 06-01, 01800, 3-06-02, 13-06-02, 01801, 3-06- 03, 13-06-03, 01802, 3- 06-04, 13-06-04, 01803, 3-06-05, 13-06- 05, 01804, 3-06-07, 13- 06-07, 01805, 3-11-01, 13-11-01, 1826, 3-11- 02, 01827, 3-11-03, 13- 11-03, 01828, 3-11-04, 13-11-04, 01829, 3-11- 05, 01830, 3-11-06, 13- 11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, 13-11- 09, 01834, 3-12-01, 13- 12-01, 01838, 3-12-02, 13-12-02, 01839, 3-12- 03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, 13-12- 07, 01844, 3-12-08, 01845, 3-12-09, 13-12- 09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, 13-13- 07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48- 20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10- 02, 3-10-03, 3-10-04, 3- 10-05, 3-01-01S, 3-03- 25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3- 05-06, 3-05-07, 3-05- 22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3- 05-29, 3-05-30, 3-09- 03, 01814, 3-09-04, 13- 09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09- 08, 13-09-08, 01472,	UMDNS: 16- 222 GMDN: 63247		0849771000000000000003M7
Hedeflenen Amaç: Tıbbi cihazların üstünü kapatmak ve bunları korumak üzere tasarlanmıştır.	Key Surgical Instrument Tip Caps				

01473, 3-09-09,
01474, 01475, 01494,
3-09-10, 3-24-98, 3-
24-99, 3-48-50, 3-80-
03, 3-60-01, 3-60-02,
3-60-03, 3-60-04, 3-
60-05, 3-60-06, 3-60-
07, 3-60-08, 3-60-09,
3-60-10, 3-60-11,
01471, 01476, 01477,
01469, 01470, 01478,
01479, 01492, 01496,
01499, 3-01-01,
01865, 3-01-02,
01890, 3-01-03,
01866, 3-01-04,
01867, 3-01-05,
01891, 3-01-06,
01892, 3-02-01,
01876, 3-02-02, 3-02-
03, 01877, 3-02-04,
01878, 3-02-06, 3-03-
01, 01871, 3-03-02,
01872, 3-03-03,
01873, 3-03-04,
01874, 3-03-05,
01875, 3-03-06, 3-04-
01, 01484, 3-04-02,
01485, 3-04-03,
01486, 3-04-04,
01487, 3-04-05,
01488, 3-04-06,
01489, 3-08-01,
01460, 3-08-02,
01461, 3-08-03,
01462, 3-08-04,
01463, 3-08-05,
01464, 3-08-06,
01465, 3-09-01, 3-09-
02S, 3-15-01, 01868,
3-15-02, 01869, 3-15-
03, 01870, 3-15-04,
01884, 3-15-05,
01885, 3-15-06,
01886, 3-21-03, 3-24-
06, 3-24-20, , 3-42-95,
3-44-01, 3-44-02, 3-
44-03, 3-44-04, 3-44-
05, 3-44-06, 3-44-96,
3-44-97, 3-48-01,, 3-
48-02, 3-48-03, 3-48-
04, 3-48-05, 3-48-06,
,3-48-61, 3-48-62, 3-
48-94, 3-48-95, 3-74-
05, 3-74-06, I3-03-01,
I3-03-02, I3-03-03, I3-
04-01, I3-04-02, I3-04-
03, I3-04-04, I3-04-05,
I3-04-06, I3-08-01, I3-
08-02, I3-08-03, I3-08-
04, I3-08-05, I3-08-
06,3-03-11, 3-03-12, 3-
03-13, 3-03-15, 3-04-
11, 01806, 3-04-12,
01807, 3-04-13,

		<p>01808, 01809, 3-04-17, 01811, 3-04-18, 01812, 3-04-19, 01813, 3-08-11, 3-08-12, 3-08-13, 3-08-15, 3-08-17, 3-08-18, 3-08-19, 3-24-11, 3-24-13, 3-24-15, 3-24-17, 3-44-11, 3-44-12, 3-44-13, 3-44-15, 3-44-16, 3-44-17, 3-44-18, 3-44-19, 3-48-11, 3-48-12, 3-48-13, 3-48-15, 3-48-16, 3-48-17, 3-48-18, 3-48-19, 3-74-11, 3-74-15, 3-78-11, 13-04-11, 13-04-12, 13-04-13, 13-04-15, 13-04-18, 3-04-07, 01480, 3-04-08, 01481, 3-04-09, 01482, 01810, 3-08-07, 01466, 3-08-08, 01467, 3-08-09, 01468, 3-15-07, 01887, 3-15-08, 01888, 3-15-09, 01889, 3-24-08, 3-24-09, 3-44-07, 3-44-08, 3-44-09, 3-48-07, 3-48-08, 3-48-09, 3-74-07, 3-74-09, 13-04-07, 13-04-08, 13-04-09, 13-08-07, 13-08-08, 13-08-09, 3-01-07, 3-01-08, 01824, 3-01-09, 3-02-07, 01879, 3-02-08, 3-02-09, 3-03-07, 3-03-08, 3-03-09, 3-16-05, 3-16-06, 3-16-07, 3-16-08, 01821, 3-16-09, 30000, 30001, 30002, 30003, 30004, 30005, 30006, 30007, 30008, 30009, 30010, 30012, 30013, 30014, 30015, 30016, 30017, 01850, 01851, 01852, 01853, 01854, TP-09-11, TP-09-12, TP-09-13, 3-02-05, 3-04-15, 3-06-50, 3-08-09, 3-08-100, 3-11-01, 01826</p>			
	<p>Key Surgical Instrument Tip Protectors</p>	<p>PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004</p>			

K Teli ve Pin Kapakları Hedeflenen Amaç: K tellerinin ve pinlerin üstünün kapatılması ve bunların korunması.		H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457			
	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS			
Cihaz Sterilizasyon Tepsisi Hedeflenen Amaç: Temizleme, sterilizasyon ve saklama ortamında cihazların korunması.	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS:12-143 GMDN: 13730	0849771000000000000004M9	
	Key Surgical Finger Mat	FM-1810			
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75			

		BSK600X140X50 DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Tepsi Köşe Koruyucuları Hedeflenen Amaç: Sterilizasyon tepsisi köşelerinin ve sterilizasyon sargısının korunması	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15- 907 GMDN: 63494 & 65133		0849771000000000000005MB
Yapıştırıcı Çıkarıcı Hedeflenen Amaç: Tıbbi aletlerden yapıştırıcı kalıntılarını çıkarmak üzere kullanılan çözeltili	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN:64150		0849771000000000000006MD
Sıcak Hava Filmi Hedeflenen Amaç: Sıcak Hava Sterilizasyonu yöntemlerinde kullanım için tasarlanmıştır	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735		0849771000000000000007MF
Sterilizasyon Sargısı Hedeflenen Amaç: Steril Bariyer Sargısı	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100	UMDNS: GMDN: 13735		0849771000000000000008MH

CB/TWO120
CB/TWR120
CB/TWRAP060
CB/TWRAP075
CB/TWRAP090
CB/TWRAP100
CB/TWRAP1012
CB/TWRAP120
CB/TWRAP1315
CB/TWRAP1315X
CB/TWRAP150
CB/TWRAP150F3W
CB/TWRAP18135
CB/TWRAP1815
CB/TWRAP5075
CB/TWRAPDRY050
CB/TWRAPDRY060
CB/TWRAPDRY075
CB/TWRAPDRY090
CB/TWRAPDRY100
CB/TWRAPDRY120
CB/TWRAPDRY1315X
CB/TWRAPDRY140
CB/TWY100
CB/TWY120
CB030
CB050
CB060
CB075
CB090
CB100
CB100DB
CB1012
CB1014
CB120
CB120DB
CB1315
CB1315DB
CB140
CB150
CB1540
CB1715
CB1715DB
CB1815
CB1815DB
CBA/TWRAP120
CBA/TWRAP140
CBA050
CBA075
CBA090
CBA100
CBA120
CBA1415
CBU/TWRAP100
CBU/TWRAP1215
CBU/TWRAP1315
CBU/TWY120
CBU1014
CBU1014DB
CBU120
CBU1315
CBU150
CDB/CG060
CDB/CG075
CDB/CG075DB

CDB/CG090
CDB/CG100
CDB/CG1012
CDB/CG1012DB
CDB/CG1014
CDB/CG120
CDB/CG120DB
CDB/CG1215
CDB/CG1215DB
CDB/CG1315
CDB/CG1315DB
CDB/CG140
CDB/CG150
CDB/CG150DB
CDB/CG1815
CDB/CG1815DB
CDB/GC120
CDB/GC140
CDB/TWO090
CDB/TWR120
CDB/TWRAP090
CDB/TWRAP100
CDB140
CDB1815
CDB5075
CDG/CB060
CDG/CB075
CDG/CB075DB
CDG/CB090
CDG/CB100
CDG/CB1012DB
CDG/CB1015
CDG/CB120
CDG/CB120DB
CDG/CB1215DB
CDG/CB1315
CDG/CB1315DB
CDG/CB1815DB
CDG/TWO1215
CDG/TWO1315X
CDG/TWRAP060
CDG/TWRAP075
CDG/TWRAP090
CDG/TWRAP100
CDG/TWRAP100DB
CDG/TWRAP1014
CDG/TWRAP120
CDG/TWRAP120DB
CDG/TWRAP1214
CDG/TWRAP1215
CDG/TWRAP1315
CDG/TWRAP150
CDG/TWY1315
CDG075
CDG090
CDG100
CDG120
CDG1215
CDG140
CDG150
CDG1815
CG/CB050
CG/CB060
CG/CB075
CG/CB075DB

CG/CB090
CG/CB100
CG/CB100DB
CG/CB1012
CG/CB1014
CG/CB1014DB
CG/CB1075
CG/CB1075DB
CG/CB1090
CG/CB120
CG/CB1215
CG/CB1215X
CG/CB1315
CG/CB1315/P120
CG/CB1315DB
CG/CB1315X
CG/CB140
CG/CB140X
CG/CB150
CG/CB1715
CG/CB1715/F4
CG/CB1815
CG/CB1815/P72
CG/CB5045
CG/CBA120
CG/CBU075
CG/CBU090
CG/CBU100
CG/CBU100DB
CG/CBU1012
CG/CBU1014
CG/CBU1090
CG/CBU1215
CG/CBU1315DB
CG/CBU1315X
CG/PRO1215
CG/PRO1815
CG/TWO060
CG/TWO090
CG/TWO1012
CG/TWO1012DB
CG/TWO1014
CG/TWO1014DB
CG/TWO1075
CG/TWO1075DB
CG/TWO1090DB
CG/TWO120
CG/TWO1215
CG/TWO1215DB
CG/TWO1215PZDB
CG/TWO1315
CG/TWO140
CG/TWO1715
CG/TWO1715DB
CG/TWO1815
CG/TWO1815DB
CG/TWR060
CG/TWR090DB
CG/TWR100
CG/TWR100DB
CG/TWR1014
CG/TWR1090DB
CG/TWR1215PZDB
CG/TWR1315
CG/TWR1315PZDB

CG/TWR1715DB
CG/TWR1815PZDB
CG/TWRAP060
CG/TWRAP075
CG/TWRAP075DB
CG/TWRAP090
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CG/TWRAP100
CG/TWRAP100DB
CG/TWRAP1012
CG/TWRAP1012DB
CG/TWRAP1014
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CG/TWRAP1075
CG/TWRAP1090
CG/TWRAP1090DB
CG/TWRAP120
CG/TWRAP120DB
CG/TWRAP1215
CG/TWRAP1215DB
CG/TWRAP1215PZDB
CG/TWRAP1315
CG/TWRAP1315DB
CG/TWRAP1315PZ
CG/TWRAP1315PZDB
CG/TWRAP140
CG/TWRAP140DB
CG/TWRAP150
CG/TWRAP1715DB
CG/TWRAP1815
CG/TWRAP1815/F4
CG/TWRAP1815DB
CG/TWRAP5075
CG/TWRAP5075DB
CG/TWRAPDRY060DB
CG/TWRAPDRY075
CG/TWRAPDRY090
CG/TWRAPDRY090DB
CG/TWRAPDRY100
CG/TWRAPDRY1012
CG/TWRAPDRY1014
CG/TWRAPDRY1075
CG/TWRAPDRY1090
CG/TWRAPDRY120
CG/TWRAPDRY120DB
CG/TWRAPDRY1215
CG/TWRAPDRY1315
CG/TWRAPDRY1315D
CG/TWRAPDRY1315X
CG/TWRAPDRY140
CG/TWRAPDRY150
CG/TWRAPDRY1715
CG/TWRAPDRY1815
CG/TWRAPDRY1815M
CG/TWY060
CG/TWY075DB
CG/TWY090
CG/TWY090DB
CG/TWY100
CG/TWY100DB
CG/TWY1012
CG/TWY1012DB
CG/TWY1090
CG/TWY1090DB
CG/TWY1215

CG/TWY1215PZDB
CG/TWY1315
CG/TWY1315DB
CG/TWY1815
CG/WB120
CG/WB1315
CG/WB1815
CG060
CG075
CG075DB
CG090
CG090/P150
CG100
CG100/P150
CG100DB
CG120
CG120DB
CG1215
CG1315
CG140
CG150
CG1715DB
CG1815DB
CG5075
CGP/CB100
CGP/CB120
CGP/CB1715
CGP/CB1815
CGP/CBU100
CGP/CBU1014
CGP/CBU1014DB
CGP/CBU1090
CGP/CBU1215
CGP/CBU1315
CGP/CBU140
CGP/CBU1815
CGP/TWO100
CGP/TWO1012
CGP/TWO1215
CGP/TWO1815
CGP/TWRAP060
CGP/TWRAP060DB
CGP/TWRAP075
CGP/TWRAP075DB
CGP/TWRAP090
CGP/TWRAP100
CGP/TWRAP1012
CGP/TWRAP1075
CGP/TWRAP120
CGP/TWRAP1215
CGP/TWRAP1315
CGP/TWRAP150
CGP/TWRAP1815
CGP/TWY075
CGP/TWY100
CGP/TWY1315
CGP/TWY1815
CGP1315
CGP150
CGX/CB075
CGX/CB075DB
CGX/CB090
CGX/CB100
CGX/CB100DB
CGX/CB1012

CGX/CB1012DB
 CGX/CB1014
 CGX/CB1090
 CGX/CB1090DB
 CGX/CB1215
 CGX/CB1215DB
 CGX/CB1315
 CGX/CB1315/P120
 CGX/CB1315P120DB
 CGX/CB1715
 CGX/CB1715DB
 CGX/CB1815
 CGX/CB1815DB
 CGX/CB5075
 CGX/CB5075DB
 CGX/CBU060
 CGX/CBU060DB
 CGX/CBU100
 CGX/CBU1012
 CGX/CBU1014
 CGX/CBU1014DB
 CGX/CBU1090
 CGX/CBU1090DB
 CGX/CBU1215
 CGX/CBU1315
 CGX/CBU1315DB
 CGX/CBU1815
 CGX/TWO1012DB
 CGX/TWO1090DB
 CGX/TWO1215PZDB
 CGX/TWO1315
 CGX/TWR1090DB
 CGX/TWR1215PZDB
 CGX/TWR1715DB
 CGX/TWRAP075DB
 CGX/TWRAP090
 CGX/TWRAP090DB
 CGX/TWRAP100
 CGX/TWRAP100DB
 CGX/TWRAP1012
 CGX/TWRAP1012DB
 CGX/TWRAP1090DB
 CGX/TWRAP1215
 CGX/TWRAP1215PZDB
 CGX/TWRAP1315
 CGX/TWRAP1315PZDB
 CGX/TWRAP1715DB
 CGX/TWRAP1815
 CGX/TWRAP1815DB
 CGX/TWRAP5075
 CGX/TWRAP5075DB
 CGX/TWRAPD100DB
 CGX/TWRAPD1215DB
 CGX/TWRAPD1315DB
 CGX/TWRAPDRY100
 CGX/TWRAPDRY1215
 CGX/TWRAPDRY1315
 CGX/TWY090DB
 CGX/TWY1012DB
 CGX/TWY1090DB
 CGX/TWY1215PZDB
 CGX/TWY1315
 CGX/TWY1315DB
 CGX090
 CGX100

CGX100DB
 CGX120
 CGX1715DB
 REL340G/CBU100
 REL340G/CBU1014
 REL340G/CBU1215
 REL340G/CBU1315
 RELGRN/CB100
 RELGRN/CB1050
 RELGRN/CB1315
 RELGRN/CB140
 RELGRN/WB1815
 WB/TDRY100DB
 WB/TWO075
 WB/TWO1012
 WB/TWO1014
 WB/TWO1014DB
 WB/TWO1315
 WB/TWRAP060
 WB/TWRAP075
 WB/TWRAP090
 WB/TWRAP100
 WB/TWRAP100DB
 WB/TWRAP1012
 WB/TWRAP1014DB
 WB/TWRAP1075
 WB/TWRAP1215
 WB/TWRAP1215DB
 WB/TWRAP1315
 WB/TWRAP1815
 WB/TWRAPDRY060
 WB/TWRAPDRY090
 WB/TWRAPDRY100
 WB/TWRAPDRY120
 WB/TWRAPDRY1315X
 WB/TWRAPDRY150
 WB/TWRAPDRY150F3
 WB/TWY090
 WB/TWY1014
 WB/TWY1215
 WB075
 WB090
 WB100
 WB1014
 WB120
 WB140
 CBA060
 CBU140
 CDG1315
 CG/TWRAPDRY060
 CGX/TWY1215
 WB/TWRAPDRY1012
 MC-CBA/TWRAP090
 MC-CBA/TWRAP100
 MC-CBA/TWRAP120
 RELGRN/CBU100
 RELGRN/CBU140
 CG/CBU120
 CGX/TWY090
 CGX/TWY1012
 CG/CBU1815
 CB/TDRY075
 CB/TDRY090
 CB/TDRY100
 CB/TDRY060

		CB/TDRY120 CGX/TWR1815			
Nakliye Sargısı Hedeflenen Amaç: Nakliye Bariyer Sargısı	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB TWRAP1014 TWRAP1090DB	GMDN: 13735		0849771000000000000009MK

TWRAP120
TWRAP1215
TWRAP1215DB
TWRAP1315
TWRAP1315DB
TWRAP140
TWRAP140DB
TWRAP150
TWRAP150DB
TWRAP1715
TWRAP1715DB
TWRAP1815
TWRAP1815DB
TWRAP5090
TWRAP5390
TWRAP7537
TWRAP75375
TWRAPDRY050
TWRAPDRY060
TWRAPDRY075
TWRAPDRY090
TWRAPDRY100
TWRAPDRY1012
TWRAPDRY1014
TWRAPDRY120
TWRAPDRY1315
TWRAPDRY140
TWRAPDRY1815
TWRAPDRY3015
TWRAPDRY3015SGL
TWRAPDRY5075
TWRAPDRY7560
TWRAPDRYOFFCUT
TWY075
TWY075DB
TWY090
TWY100
TWY100DB
TWY1012
TWY1014
TWY120
TWY1215
TWY1215DB
TWY1315
TWY1315DB
TWY140
TWY1715
TWY1715DB
TWY1815
CDBAG002G
H-THCOVER001
H-THCOVER002
H-THCOVER003
H-THOCOVER001
H-THOCOVER002
H-THOCOVER003
H-THRCOVER001
H-THRCOVER002
H-THRCOVER003
H-THYCOVER001
H-THYCOVER002
H-THYCOVER003
PC000700
PC000800
PC000900

		PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Nakliye Sargısı Hedeflenen Amaç: Nakliye Bariyer Sargısı	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN: 13735		
Kap Filtreleri Hedeflenen Amaç: Sterilizasyon kapları ile kullanım içindir.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157 01158	GMDN: 60909	0849771000000000000010M4	

01167
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01363
01365
01366
01367
01368
01369
01373
04111
1070020
26510
27320
27330
27340
27350
27360
55-291-01-04
61140
71140
71141
71194
91140
26515
27325
27335
27345
27355
27365
91140
26510
ME01194
ME26515
ME27325
ME27335

		ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Tepsi Örtüleri Hedeflenen Amaç: Tıbbi cihazların sterilizasyonunda kullanım içindir.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007 H-TLC008 H-TLC009 H-TLC010 H-TLC011 H-TLC012 H-TLC013 H-TLC078 H-TLC109 H-TLC110 H-TLC111 H-TLC119 H-TLC213 H-TLC214 H-TLC215 LIB1328 LIB250X320 LIB300X360 LIB300X500 LIB3025 LIB3050 LIB400X500 LINH3020 LINH3041 LINH4555 MILB002 MILB003 MILB004 MILB005 MILB006 MILB007 MILB008 MILB009 MILB011 MILB012 MILB016 MILB017	GMDN: 60908	0849771000000000000011M6	

MILB019
MILB020
MILB021
MILB022
MILB025
MILB027
MILB029
MILB056
MILB120X250
MILB130X230
MILB170X270
MILB250X300
MILB300X400
MILB305X450
MILB350x450
MILB375X600
MILB450X650
MILB500X900
PC002100
PC002200
PC008800
PC008900
PC009000
PC009100
PC009200
PC009400
PC009800
PC009900
PC010000
PC010200
PC010400
PC010700
PC010800
PC011200
PC011300
PC011400
PC011700
PC011800
PC013300
PC013600
TL-101-200
TL-202-500
TL-203-500
TL-204-500
TLC001
TLC002
TLC004
TLC005
TLC006
TLC007
TLC008
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TLC027

		TLC029R TLC030 TLC031 TLC034 TLC036 TLC045 TLC051 TLC052 TLC055 TLC060 TLC066 TLC069 TLC071 TLC072 TLC078 TLC079 TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300 PC013100 PC013200	GMDN: 61664		

		SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK0015SS			
Bakım Yağı					
Hedeflenen Amaç: Tıbbi cihazların yağlanması için kullanılmak üzere tasarlanmıştır.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	08497710000000000000000012M8	
Chiol Ultra					
Hedeflenen Amaç: Metal yüzeylerden kirlerin çıkarılması için kullanılan temizleme solüsyonu.	Chiol Ultra	02110	GMDN:63385	08497710000000000000000013MA	

İşbu belge ile

Tıbbi Cihaz Güvenlik Servisini (MDSS)
Schiffgraben 41
D-30175 Hannover
Almanya

MDR'nin 2(32). maddesinde tanımlanan şekilde Avrupa Yetkili Temsilcisi olarak atamaktayız.

Uygunluk Değerlendirme Yolu: Ek IV

Yayınlayan:

İmza:



Tarih: 2021-12-28

Ad:

Coletta Cohara

Görev:

Direktör kalitesi ve mevzuat uyumu

Uygunluk Beyanının

Key Surgical LLC

Yayınlanma Yeri:

8101 Wallace Rd.

Eden Prairie, MN 55344

USA