



**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, non-measuring medical devices meet the provisions of the Council Directive 93/42/EEC (MDD) Annex VII for Medical Devices as amended by 2007/47/EC, which apply to them. These products also conform with the following applicable standards: EN ISO 13485:2016, ISO 14971:2007, EN ISO 14971:2012, and BS EN ISO 15223-1:2016. 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  Intended Purpose: Cleaning of medical devices	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033	UMDNS: 10-502 GMDN: 34878	0849771000000000000000001M3	Applied recognized standards are identified in technical documentation.
	Key Surgical Instrument and Channel Cleaning Brushes	26020	UMDNS: 21-134 GMDN: 34878 & 38835		
		26021			
		26022			
		26025			
		26026			
		26027			
		26028			
		26090			
		26305			
		26481			
		26482			
		09050			
		09051			
		09052			
		09053			
		09054			
		09055			
		09056			
		09058			
		09059			
		09066			
		09068			
		09083			
		09096			
		09098			
		09306			
		09307			
		09308			
		09309			
		09310			
		09311			
		09312			
09313					
09314					
09315					
09316					
09317					
09318					
09324					
09331					

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		09332			
		09333			
		09334			
		09335			
		09336			
		09338			
		09339			
		09340			
		09341			
		09342			
		09343			
		09344			
		09345			
		09346			
		09352			
		09353			
		09356			
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			
		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-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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			
		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-4300			
		BR-4310			
		BR-4320			
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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 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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			
		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			



Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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 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			
	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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		US-2100 US-2100-50 US-2300			
	Key Surgical Endoscope Cleaning Brushes	26022, 26020, 26021, 26482, 26025, 26028, 26481, 26027, 26090, 26305, 26026, 09356, 09353, 09352, 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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			
	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21-134 GMDN: 34878		
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	08497710000000000000002M5	
Instrument Protectors  Intended Purpose: Intended to cover and	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,	UMDNS: 16-222 GMDN: 43387		

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
protect medical instruments.		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, 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, 01893, 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,		0849771000000000000003M7	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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, 3-24-07, 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, 01818, 01824, 3-01-09, 3-02-07, 01879, 3-02-08, 01880, 3-02-09, 01881, 3-03-07, 3-03-08, 3-03-09, 3-16-05, 3-16-06, 3-16-07, 01820, 01817, 3-16-08, 01821, 3-16-09, 01822, 01819, 01825, 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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
K-Wire and Pin Covers Intended Purpose: Protect and cover K-wires and pins.	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 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	UMDNS:12-143 GMDN:12143	084977100000000000000004M9	
	Key Surgical Finger Mat	FM-1810			
	Key Surgical Mesh Trays	08132, 08434, 08435, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899,			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, 08991, 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, BELBSK116, BELBSK117, BELTRY010, BELTRY013, BSK316, BSK316H, BSK317, BSK317H, BSK318, BSK318H, BSK580X330X75, BSK600X140X50, DIV116, DIV116/4, NIC001R, NIC002, NIC003, NIC003DEEP, NIC004DEEP, NIC004DEEPSJ			
	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, H-CC003, PC001600, CC001, CC002, CS-9113, CS-9125C	UMDNS: 15-907 GMDN: 63494	0849771000000000000005MB	
Adhesive Remover	Adhesive Remover	02111	GMDN:64150	0849771000000000000006MD	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
Intended Purpose: Solution for removing adhesive residue from medical instruments					
Hot Air Film  Intended Purpose: Intended for use in Hot Air Sterilization methods	Key Surgical Hot Air Film	36202, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209	UMDNS: GMDN: 13735	0849771000000000000007MF	
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 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	UMDNS: GMDN: 13735	0849771000000000000008MH	



Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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 CDB060 CDB075 CDB090 CDB100 CDB1012 CDB1014 CDB120 CDB1315			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CDB140 CDB150 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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CG075DB CG090 CG090/P150 CG100 CG100/P150 CG100DB CG120 CG120DB CG1215 CG1315 CG140 CG150 CG1715DB CG1815DB CG5075 CGA/CBA050P100 CGA/CBA060P100 CGA/CBA075P100 CGA/CBA5075P100 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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CGX/TWY1315DB CGX090 CGX100 CGX100DB CGX120 CGX1715DB FILT003G FILT004 MC-CBA/TWRAP090 MC-CBA/TWRAP100 MC-CBA/TWRAP120 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			
Transportation Wrap  Intended Purpose: Transportation Barrier Wrap	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060	GMDN: 13735	0849771000000000000009MK	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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 TWRAP120 TWRAP1215 TWRAP1215DB TWRAP1315 TWRAP1315DB			



Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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			
		DGM-TCOVER4270			
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
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	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149	GMDN: 60909	0849771000000000000010M4	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
sterilization containers.		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 01366 01367 01368 01369 01373 04111 1070020 26510 27320 27330 27340 27350 27360 55-291-01-04 61140 71140 71141 71194 91140			
Tray Liners	Tray Liners	49937 49938 50110 51448	GMDN:61664	0849771000000000000011M6	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
Intended Purpose: For use in sterilization of medical devices.		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 MILB019 MILB020 MILB021 MILB022 MILB025 MILB027 MILB029 MILB056 MILB120X250			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		MILB130X230			
		MILB170X270			
		MILB250X300			
		MILB300X400			
		MILB305X450			
		MILB350x450			
		MILB375X600			
		MILB450X650			
		MILB500X900			
		M-MILB300X600			
		M-MILB400X300			
		M-MILB500X400			
		M-TLC004			
		M-TLC007			
		M-TLC008			
		M-TLC010			
		M-TLC036			
		M-TLC045			
		M-TLC051			
		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			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		TLC020 TLC022 TLC023 TLC024 TLC027 TLC029 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			
	Soaker Sheets	H-CT005 H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS	GMDN:61664		

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		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 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640			
Maintenance Oil  Intended Purpose: Intended for use in lubricating medical devices.	Lubrinol	02004	GMDN: 15772	0849771000000000000012M8	
Chirol Ultra  Intended Purpose: Cleaning solution for removing soils from metallic surfaces.	Chirol Ultra	02110	GMDN: 63385	0849771000000000000013MA	

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

as the European Authorized Representative as defined in Article 1(j) of the MDD.

**Conformity Assessment Route:**    Annex VII

**Issued By:**



**Signature:**

**Date:** 01/13/2021

**Name:**            Kasey Koenig  
**Position:**        Director, Global Quality, Regulatory and DPO  
**Place of**            Key Surgical LLC  
**Issue of**            8101 Wallace Rd.  
**DoC:**                Eden Prairie, MN 55344  
                                 USA