

UK DECLARATION OF CONFORMITY

Medical Devices Regulations 2002 Class I non-sterile, non-measuring devices

Manufacturer: Key Surgical LLC
8101 Wallace Road
Eden Prairie, MN 55344
United States

UK Responsible Person: MDSS UK RP Ltd
6 Wilmslow Road, Rusholme,
Manchester
M14 5TP
United Kingdom

Product: **Sterilization Wrap & Transportation Wrap and Covers**
(See Appendix A for list of SKUs)

Classification: Class I non-sterile, non-measuring
Rule: 1
Conformity: Annex VII – Self Certified

Key Surgical declares that the above-mentioned product(s) meet the provisions of the Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). The product has been subjected to conformity assessment procedures set out in the Medical Devices Regulations 2002. All supporting documentation is retained on the premises of the manufacturer.

ISO 13485 Certificate(s) #: MD 666821
Expiry: 2023-05-11

Start of UKCA marking: November 10, 2022

Place, Date of issue: Eden Prairie, MN USA

Regulatory Approval

Signature:



Name and Title: Steve Deline, MS RAS
Manager, Regulatory Affairs

Date: November 9, 2022

Appendix A – List of Applicable SKUs

Product Name	GMDN	Item Numbers			
Sterilization Wrap	13735 (Sterilization packaging, single-use)	CB/PRO075	CDG/TWRAP090	CG/TWRAP1815	CGX/CBU060DB
		CB/PRO100	CDG/TWRAP100	CG/TWRAP1815/F4	CGX/CBU100
		CB/PRO1012	CDG/TWRAP100DB	CG/TWRAP1815DB	CGX/CBU1012
		CB/PRO1215	CDG/TWRAP1014	CG/TWRAP5075	CGX/CBU1014
		CB/PRO1315	CDG/TWRAP120	CG/TWRAP5075DB	CGX/CBU1014DB
		CB/SDG/TW1315	CDG/TWRAP120DB	CG/TWRAPDRY060DB	CGX/CBU1090
		CB/TWO060	CDG/TWRAP1214	CG/TWRAPDRY075	CGX/CBU1090DB
		CB/TWO075	CDG/TWRAP1215	CG/TWRAPDRY090	CGX/CBU1215
		CB/TWO090	CDG/TWRAP1315	CG/TWRAPDRY090DB	CGX/CBU1315
		CB/TWO100	CDG/TWRAP150	CG/TWRAPDRY100	CGX/CBU1315DB
		CB/TWO120	CDG/TWY1315	CG/TWRAPDRY1012	CGX/CBU1815
		CB/TWR120	CDG075	CG/TWRAPDRY1014	CGX/TWO1012DB
		CB/TWRAP060	CDG090	CG/TWRAPDRY1075	CGX/TWO1090DB
		CB/TWRAP075	CDG100	CG/TWRAPDRY1090	CGX/TWO1215PZDB
		CB/TWRAP090	CDG120	CG/TWRAPDRY120	CGX/TWO1315
		CB/TWRAP100	CDG1215	CG/TWRAPDRY120DB	CGX/TWR1090DB
		CB/TWRAP1012	CDG140	CG/TWRAPDRY1215	CGX/TWR1215PZDB
		CB/TWRAP120	CDG150	CG/TWRAPDRY1315	CGX/TWR1715DB
		CB/TWRAP1315	CDG1815	CG/TWRAPDRY1315D	CGX/TWRAP075DB
		CB/TWRAP1315X	CG/CB050	CG/TWRAPDRY1315X	CGX/TWRAP090
		CB/TWRAP150	CG/CB060	CG/TWRAPDRY140	CGX/TWRAP090DB
		CB/TWRAP150F3W	CG/CB075	CG/TWRAPDRY150	CGX/TWRAP100
		CB/TWRAP18135	CG/CB075DB	CG/TWRAPDRY1715	CGX/TWRAP100DB
		CB/TWRAP1815	CG/CB090	CG/TWRAPDRY1815	CGX/TWRAP1012
		CB/TWRAP5075	CG/CB100	CG/TWRAPDRY1815M	CGX/TWRAP1012DB
		CB/TWRAPDRY050	CG/CB100DB	CG/TWY060	CGX/TWRAP1090DB
		CB/TWRAPDRY060	CG/CB1012	CG/TWY075DB	CGX/TWRAP1215
		CB/TWRAPDRY075	CG/CB1014	CG/TWY090	CGX/TWRAP1215PZDB
		CB/TWRAPDRY090	CG/CB1014DB	CG/TWY090DB	CGX/TWRAP1315
		CB/TWRAPDRY100	CG/CB1075	CG/TWY100	CGX/TWRAP1315PZDB
		CB/TWRAPDRY120	CG/CB1075DB	CG/TWY100DB	CGX/TWRAP1715DB
		CB/TWRAPDRY1315X	CG/CB1090	CG/TWY1012	CGX/TWRAP1815
		CB/TWRAPDRY140	CG/CB120	CG/TWY1012DB	CGX/TWRAP1815DB
		CB/TWY100	CG/CB1215	CG/TWY1090	CGX/TWRAP5075
		CB/TWY120	CG/CB1215X	CG/TWY1090DB	CGX/TWRAP5075DB
		CB030	CG/CB1315	CG/TWY1215	CGX/TWRAPD100DB
		CB050	CG/CB1315/P120	CG/TWY1215PZDB	CGX/TWRAPD1215DB
		CB060	CG/CB1315DB	CG/TWY1315	CGX/TWRAPD1315DB
		CB075	CG/CB1315X	CG/TWY1315DB	CGX/TWRAPDRY100
		CB090	CG/CB140	CG/TWY1815	CGX/TWRAPDRY1215
		CB100	CG/CB140X	CG/WB120	CGX/TWRAPDRY1315
		CB100DB	CG/CB150	CG/WB1315	CGX/TWY090DB
		CB1012	CG/CB1715	CG/WB1815	CGX/TWY1012DB
		CB1014	CG/CB1715/F4	CG060	CGX/TWY1090DB
		CB120	CG/CB1815	CG075	CGX/TWY1215PZDB
		CB120DB	CG/CB1815/P72	CG075DB	CGX/TWY1315
		CB1315	CG/CB5045	CG090	CGX/TWY1315DB
		CB1315DB	CG/CBA120	CG090/P150	CGX090
		CB140	CG/CBU075	CG100	CGX100
		CB150	CG/CBU090	CG100/P150	CGX100DB

Product Name	GMDN	Item Numbers			
Sterilization Wrap	13735 (Sterilization packaging, single-use)	CB1540	CG/CBU100	CG100DB	CGX120
		CB1715	CG/CBU100DB	CG120	CGX1715DB
		CB1715DB	CG/CBU1012	CG120DB	REL340G/CBU100
		CB1815	CG/CBU1014	CG1215	REL340G/CBU1014
		CB1815DB	CG/CBU1090	CG1315	REL340G/CBU1215
		CBA/TWRAP120	CG/CBU1215	CG140	REL340G/CBU1315
		CBA/TWRAP140	CG/CBU1315DB	CG150	RELGRN/CB100
		CBA050	CG/CBU1315X	CG1715DB	RELGRN/CB1050
		CBA075	CG/PRO1215	CG1815DB	RELGRN/CB1315
		CBA090	CG/PRO1815	CG5075	RELGRN/CB140
		CBA100	CG/TWO060	CGP/CB100	RELGRN/WB1815
		CBA120	CG/TWO090	CGP/CB120	WB/TDRY100DB
		CBA1415	CG/TWO1012	CGP/CB1715	WB/TWO075
		CBU/TWRAP100	CG/TWO1012DB	CGP/CB1815	WB/TWO1012
		CBU/TWRAP1215	CG/TWO1014	CGP/CBU100	WB/TWO1014
		CBU/TWRAP1315	CG/TWO1014DB	CGP/CBU1014	WB/TWO1014DB
		CBU/TWY120	CG/TWO1075	CGP/CBU1014DB	WB/TWO1315
		CBU1014	CG/TWO1075DB	CGP/CBU1090	WB/TWRAP060
		CBU1014DB	CG/TWO1090DB	CGP/CBU1215	WB/TWRAP075
		CBU120	CG/TWO120	CGP/CBU1315	WB/TWRAP090
		CBU1315	CG/TWO1215	CGP/CBU140	WB/TWRAP100
		CBU150	CG/TWO1215DB	CGP/CBU1815	WB/TWRAP100DB
		CDB/CG060	CG/TWO1215PZDB	CGP/TWO100	WB/TWRAP1012
		CDB/CG075	CG/TWO1315	CGP/TWO1012	WB/TWRAP1014DB
		CDB/CG075DB	CG/TWO140	CGP/TWO1215	WB/TWRAP1075
		CDB/CG090	CG/TWO1715	CGP/TWO1815	WB/TWRAP1215
		CDB/CG100	CG/TWO1715DB	CGP/TWRAP060	WB/TWRAP1215DB
		CDB/CG1012	CG/TWO1815	CGP/TWRAP060DB	WB/TWRAP1315
		CDB/CG1012DB	CG/TWO1815DB	CGP/TWRAP075	WB/TWRAP1815
		CDB/CG1014	CG/TWR060	CGP/TWRAP075DB	WB/TWRAPDRY060
		CDB/CG120	CG/TWR090DB	CGP/TWRAP090	WB/TWRAPDRY090
		CDB/CG120DB	CG/TWR100	CGP/TWRAP100	WB/TWRAPDRY100
		CDB/CG1215	CG/TWR100DB	CGP/TWRAP1012	WB/TWRAPDRY120
		CDB/CG1215DB	CG/TWR1014	CGP/TWRAP1075	WB/TWRAPDRY1315X
		CDB/CG1315	CG/TWR1090DB	CGP/TWRAP120	WB/TWRAPDRY150
		CDB/CG1315DB	CG/TWR1215PZDB	CGP/TWRAP1215	WB/TWRAPDRY150F3
		CDB/CG140	CG/TWR1315	CGP/TWRAP1315	WB/TWY090
		CDB/CG150	CG/TWR1315PZDB	CGP/TWRAP150	WB/TWY1014
		CDB/CG150DB	CG/TWR1715DB	CGP/TWRAP1815	WB/TWY1215
		CDB/CG1815	CG/TWR1815PZDB	CGP/TWY075	WB075
		CDB/CG1815DB	CG/TWRAP060	CGP/TWY100	WB090
		CDB/GC120	CG/TWRAP075	CGP/TWY1315	WB100
		CDB/GC140	CG/TWRAP075DB	CGP/TWY1815	WB1014
		CDB/TWO090	CG/TWRAP090	CGP1315	WB120
		CDB/TWR120	CG/TWRAP090DB	CGP150	WB140
		CDB/TWRAP090	CG/TWRAP100	CGX/CB075	CBA060
		CDB/TWRAP100	CG/TWRAP100DB	CGX/CB075DB	CBU140
		CDB140	CG/TWRAP1012	CGX/CB090	CDG1315
		CDB1815	CG/TWRAP1012DB	CGX/CB100	CG/TWRAPDRY060
		CDB5075	CG/TWRAP1014	CGX/CB100DB	CGX/TWY1215
CDG/CB060	CG/TWRAP1014DB	CGX/CB1012	WB/TWRAPDRY1012		
CDG/CB075	CG/TWRAP1075	CGX/CB1012DB	MC-CBA/TWRAP090		
CDG/CB075DB	CG/TWRAP1090	CGX/CB1014	MC-CBA/TWRAP100		
CDG/CB090	CG/TWRAP1090DB	CGX/CB1090	MC-CBA/TWRAP120		

Product Name	GMDN	Item Numbers					
Sterilization Wrap	13735 (Sterilization packaging, single-use)	CDG/CB100	CG/TWRAP120	CGX/CB1090DB	RELGRN/CBU100		
		CDG/CB1012DB	CG/TWRAP120DB	CGX/CB1215	RELGRN/CBU140		
		CDG/CB1015	CG/TWRAP1215	CGX/CB1215DB	CG/CBU120		
		CDG/CB120	CG/TWRAP1215DB	CGX/CB1315	CGX/TWY090		
		CDG/CB120DB	CG/TWRAP1215PZDB	CGX/CB1315/P120	CGX/TWY1012		
		CDG/CB1215DB	CG/TWRAP1315	CGX/CB1315P120DB	CG/CBU1815		
		CDG/CB1315	CG/TWRAP1315DB	CGX/CB1715	CB/TDRY075		
		CDG/CB1315DB	CG/TWRAP1315PZ	CGX/CB1715DB	CB/TDRY090		
		CDG/CB1815DB	CG/TWRAP1315PZDB	CGX/CB1815	CB/TDRY100		
		CDG/TWO1215	CG/TWRAP140	CGX/CB1815DB	CB/TDRY060		
		CDG/TWO1315X	CG/TWRAP140DB	CGX/CB5075	CB/TDRY120		
		CDG/TWRAP060	CG/TWRAP150	CGX/CB5075DB	CGX/TWR1815		
		CDG/TWRAP075	CG/TWRAP1715DB	CGX/CBU060			
		Transportation Wrap and Covers	13735 (Sterilization packaging, single-use)	PC000100	TWR075	TWRAP1715	TWY140
				PC000200	TWR075DB	TWRAP1715DB	TWY1715
PC000300	TWR090			TWRAP1815	TWY1715DB		
PC000500	TWR100			TWRAP1815DB	TWY1815		
PC000600	TWR100DB			TWRAP5090	CDBAG002G		
PC00900	TWR1012DB			TWRAP5390	H-THCOVER001		
PRO060	TWR1014			TWRAP7537	H-THCOVER002		
PRO090	TWR1090DB			TWRAP75375	H-THCOVER003		
TDRY075	TWR120			TWRAPDRY050	H-THCOVER001		
TDRY090	TWR1215DB			TWRAPDRY060	H-THCOVER002		
TDRY100	TWR1315			TWRAPDRY075	H-THCOVER003		
TDRY120	TWR140			TWRAPDRY090	H-THRCOVER001		
TDRY3024	TWR150			TWRAPDRY100	H-THRCOVER002		
TDRYPACK1012	TWR1715DB			TWRAPDRY1012	H-THRCOVER003		
TDRYPACK1815	TWR1815			TWRAPDRY1014	H-THYCOVER001		
TWO050	TWR5075DB			TWRAPDRY120	H-THYCOVER002		
TWO060	TWRAP050			TWRAPDRY1315	H-THYCOVER003		
TWO075	TWRAP060			TWRAPDRY140	PC000700		
TWO075DB	TWRAP075			TWRAPDRY1815	PC000800		
TWO090	TWRAP075DB			TWRAPDRY3015	PC000900		
TWO100	TWRAP090			TWRAPDRY3015SSGL	PC011500		
TWO1012	TWRAP100			TWRAPDRY5075	PC011600		
TWO1012DB	TWRAP100DB			TWRAPDRY7560	TCOVER001		
TWO1014	TWRAP1012			TWRAPDRYOFFCUT	TCOVER002		
TWO120	TWRAP1012DB			TWY075	TCOVER003		
TWO1215	TWRAP1014			TWY075DB	TCOVER007		
TWO1215DB	TWRAP1090DB			TWY090	TCOVER008		
TWO1315	TWRAP120			TWY100	TCOVERDRY001		
TWO140	TWRAP1215			TWY100DB	TCOVERDRY002		
TWO140DB	TWRAP1215DB			TWY1012	TCOVERDRY003		
TWO150	TWRAP1315			TWY1014	TCOVER-RED001		
TWO150DB	TWRAP1315DB			TWY120	TCOVER-RED002		
TWO1715DB	TWRAP140			TWY1215	TCOVER-RED003		
TWO1815	TWRAP140DB			TWY1215DB	TCOVER-YELL001		
TWO5075	TWRAP150			TWY1315	TCOVER-YELL002		
TWR060	TWRAP150DB			TWY1315DB	TCOVER-YELL003		

Product Name	GMDN	Item Numbers			
Transportation Wrap Mats	13735 (Sterilization packaging, single-use)	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