

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: **Tray Liners and Soaker Sheets**
(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			
Key Surgical Tray Liners	60908 (Sterilization container liner)	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 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 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

Product Name	GMDN	Item Numbers			
Key Surgical Soaker Sheets	60908 (Sterilization container liner)	H-SOK001SS	PC013100	SOK010SS	SOK350X640
		H-SOK002SS	PC013200	SOK011SS	SOK375X300
		H-SOK003SS	SOK001SS	SOK012SS	SOK550X380
		H-SOK006SS	SOK002SS	SOK013SS	SOK560X1000
		H-SOK008SS	SOK003SS	SOK016SS	SOK560X1230
		H-SOK009SS	SOK004SS	SOK200X350	SOK560X1300
		H-SOK010SS	SOK005SS	SOK3030	SOK560X1400
		H-SOK014SS	SOK006SS	SOK3045	SOK560X280
		PC002000	SOK007SS	SOK305X545	SOK590X1200
		PC012200	SOK008SS	SOK3060	SOK640X640
		PC012300	SOK009SS	SOK350X350	SOK0015SS