

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 Trays and Baskets**
(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 Plastic Sterilization Trays	13730 (Sterilization-disinfection container, reusable)	PST-0100SB PST-1100SB	PST-2100SB PST-3100SB	PST-3200SB PST-3200SBC-1	PST-3300SB PST-4200SB
Key Surgical Finger Mat		FM-1810			
Key Surgical Mesh Trays		08132	08905	MT-6020	BSK316H
		08580	08906	MT-7100	BSK317
	08581	08907	MT-7200	BSK317H	
	08761	08908	MT-7300	BSK318	
	08762	08909	MT-8005	BSK318H	
	08763	08910	MT-8050	BSK580X330X75	
	08772	08911	MT-8500	BSK600X140X50	
	08773	08912	MT-9000	DIV116	
	08774	08931	MT-9001	DIV116/4	
	08776	08935	MT-9010	NIC001R	
	08799	08936	MT-9100	NIC002	
	08875	08948	MT-9101	NIC003	
	08896	08950	MT-9110	NIC003DEEP	
	08897	08951	MT-9210	NIC004DEEP	
	08898	08957	MT-9521	NIC004DEEPSJ	
	08899	MT-5500	MT-9200	08583	
08900	MT-5600	BELBSK116	08806		
08901	MT-5650	BELBSK117	08940		
08902	MT-5700	BELTRY010	08942		
08903	MT-5800	BELTRY013	08943		
08904	MT-5900	BSK316	08959		
Key Surgical Score Baskets	SB-1210	SB-4210	SB-4610	SB-6520	