

## 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:** **Instrument Protectors**  
(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 Instrument Tip Caps	63247 (Surgical instrument guard, single-use, non- sterile)	3-48-32	3-05-28	3-15-01	13-04-18
		3-48-44	3-05-29	01868	3-04-07
		3-06-01	3-05-30	3-15-02	01480
		01800	3-09-03	01869	3-04-08
		3-06-02	01814	3-15-03	01481
		13-06-02	3-09-04	01870	3-04-09
		01801	13-09-04	3-15-04	01482
		3-06-03	01815	01884	01810
		13-06-03	3-09-05	3-15-05	3-08-07
		01802	01816	01885	01466
		3-06-04	3-09-07	3-15-06	3-08-08
		13-06-04	3-09-08	01886	01467
		01803	13-09-08	3-21-03	3-08-09
		3-06-05	01472	3-24-06	01468
		13-06-05	01473	3-24-20	3-15-07
		01804	3-09-09	3-42-95	01887
		3-06-07	01474	3-44-01	3-15-08
		13-06-07	01475	3-44-02	01888
		01805	01494	3-44-03	3-15-09
		3-11-01	3-09-10	3-44-04	01889
		13-11-01	3-24-98	3-44-05	3-24-08
		1826	3-24-99	3-44-06	3-24-09
		3-11-02	3-48-50	3-44-96	3-44-07
		01827	3-80-03	3-44-97	3-44-08
		3-11-03	3-60-01	3-48-01	3-44-09
		13-11-03	3-60-02	3-48-02	3-48-07
		01828	3-60-03	3-48-03	3-48-08
		3-11-04	3-60-04	3-48-04	3-48-09
		13-11-04	3-60-05	3-48-05	3-74-07
		01829	3-60-06	3-48-06	3-74-09
		3-11-05	3-60-07	3-48-61	13-04-07
		01830	3-60-08	3-48-62	13-04-08
		3-11-06	3-60-09	3-48-94	13-04-09
		13-11-06	3-60-10	3-48-95	13-08-07
		01831	3-60-11	3-74-05	13-08-08
		3-11-07	01471	3-74-06	13-08-09
		01832	01476	13-03-01	3-01-07
		3-11-08	01477	13-03-02	3-01-08
		01833	01469	13-03-03	01824
		3-11-09	01470	13-04-01	3-01-09
		13-11-09	01478	13-04-02	3-02-07
		01834	01479	13-04-03	01879
3-12-01	01492	13-04-04	3-02-08		
13-12-01	01496	13-04-05	3-02-09		
01838	01499	13-04-06	3-03-07		
3-12-02	3-01-01	13-08-01	3-03-08		
13-12-02	01865	13-08-02	3-03-09		
01839	3-01-02	13-08-03	3-16-05		
3-12-03	01890	13-08-04	3-16-06		
01840	3-01-03	13-08-05	3-16-07		
3-12-04	01866	13-08-06	3-16-08		
01841	3-01-04	3-03-11	01821		
3-12-05	01867	3-03-12	3-16-09		
01842	3-01-05	3-03-13	30000		

Product Name	GMDN	Item Numbers			
Key Surgical Instrument Tip Caps	63247 (Surgical instrument guard, single-use, non-sterile)	3-12-06	01891	3-03-15	30001
		01843	3-01-06	3-04-11	30002
		3-12-07	01892	01806	30003
		13-12-07	3-02-01	3-04-12	30004
		01844	01876	01807	30005
		3-12-08	3-02-02	3-04-13	30006
		01845	3-02-03	01808	30007
		3-12-09	01877	01809	30008
		13-12-09	3-02-04	3-04-17	30009
		01846	01878	01811	30010
		3-13-03	3-02-06	3-04-18	30012
		01835	3-03-01	01812	30013
		3-13-05	01871	3-04-19	30014
		01836	3-03-02	01813	30015
		3-13-07	01872	3-08-11	30016
		13-13-07	3-03-03	3-08-12	30017
		01837	01873	3-08-13	TP-09-11
		3-14-03	3-03-04	3-08-15	TP-09-12
		01847	01874	3-08-17	TP-09-13
		3-14-05	3-03-05	3-08-18	3-02-05
		01848	01875	3-08-19	3-04-15
		3-14-07	3-03-06	3-24-11	3-06-50
		3-48-20	3-04-01	3-24-13	3-08-09
		3-07-03	01484	3-24-15	3-08-100
		3-07-05	3-04-02	3-24-17	3-11-01
		3-07-09	01485	3-44-11	01826
		01856	3-04-03	3-44-12	01861
		01857	01486	3-44-13	
		01858	3-04-04	3-44-15	
		01859	01487	3-44-16	
		01860	3-04-05	3-44-17	
		3-10-01	01488	3-44-18	
		3-10-02	3-04-06	3-44-19	
		3-10-03	01489	3-48-11	
		3-10-04	3-08-01	3-48-12	
		3-10-05	01460	3-48-13	
		3-01-01S	3-08-02	3-48-15	
		3-03-25	01461	3-48-16	
		3-04-97	3-08-03	3-48-17	
		3-04-98	01462	3-48-18	
		3-04-99	3-08-04	3-48-19	
		3-05-02	01463	3-74-11	
		3-05-06	3-08-05	3-74-15	
		3-05-07	01464	3-78-11	
		3-05-22	3-08-06	13-04-11	
		3-05-23	01465	13-04-12	
		3-05-24	3-09-01	13-04-13	
3-05-27	3-09-02S	13-04-15			
Key Surgical Instrument Tip Protectors	63247 (Surgical instrument guard, single-use, non-sterile)	PPT001	CS-1010W	H-PPT005	PC006800
		PPT002	CS-2025W	H-PPT006	PPT002/200
		PPT003	CS-3050W	H-PPT007C	PPT004/200
		PPT004	H-PPT001	H-PPT008C	PPT006/200
		PPT005	H-PPT002	PC006500	PPT008C
		PPT006	H-PPT003	PC006600	01455
		PPT007C	H-PPT004	PC006700	01457