

## 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:** **Cleaning Brushes and Sponges**  
(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 Burr Cleaning Brushes	38835 (Surgical instrument endoscope cleaning utensil, single-use)	BR-1010 BR-1031	BR-1033 BR-1050	BR-1010-50 BR-1031-50	BR-1033-50 BR-1050-50
Key Surgical Instrument and Channel Cleaning Brushes	34878 (Surgical instrument endoscope cleaning utensil, reusable)  38835 (Surgical instrument endoscope cleaning utensil, single-use)	26481 09050 09051 09052 09053 09054 09055 09056 09057 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332 09333 09334 09335 09336 09338 09339 09340 09341 09342 09343 09344 09345 09346 09365	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 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	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	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 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

Product Name	GMDN	Item Numbers				
Key Surgical Instrument and Channel Cleaning Brushes	34878 (Surgical instrument endoscope cleaning utensil, reusable)	09366	BR-16-236	FLEX022	PT-28-197-50	
		09380	BR-16-236-50	FLEX023	BR-06-039	
		09388	BR-16-276	FLEX024	PP-22-039	
		09499	BR-16-276-50	FLEX028	PP-22-062	
		09745	BR-16-393	FLEX033	PP-22-087	
		09746	BR-16-393-50	FLEXSAMP	PP-22-105	
		09747	BR-16-443	FT-12-197	PP-22-125	
		AT-12-062	BR-16-443-50	FT-12-197-50	PP-22-158	
		38835	BR-16-472	FT-12-250	PP-22-197	
		(Surgical instrument endoscope cleaning utensil, single-use)	AT-12-062-50	BR-16-472-50	FT-12-250-50	PP-24-250
			AT-12-087	BR-16-591	FT-12-276	PT-28-118
			AT-12-087-50	BR-16-591-50	FT-12-276-50	PT-28-197
			AT-12-105	BR-16-787	FT-12-375	FLEX008
			AT-12-105-50	BR-16-787-50	FT-12-375-50	FLEX009
	AT-12-118		BR-18-039	FT-12-440	FLEX025	
	AT-12-118-50		BR-18-039-50	FT-12-440-50	FLEX026	
	AT-12-125		BR-18-062	FT-12-500	BR-18-591	
	AT-12-125-50		BR-18-062-50	FT-12-500-50	BR-18-880	
	AT-12-131		BR-18-070	FT-18-197	BR-24-070	
	AT-12-131-50		BR-18-070-50	FT-18-197-50	BR-24-080	
	AT-12-158		BR-18-087	FT-18-250	BR-24-098	
	AT-12-158-50		BR-18-087-50	FT-18-250-50	BR-24-197	
	AT-12-197		BR-18-105	FT-18-276	BR-24-200	
	AT-12-197-50		BR-18-105-50	FT-18-276-50	BR-24-236	
	AT-12-250		BR-18-125	FT-18-375	BR-24-276	
	AT-12-250-50		BR-18-125-50	FT-18-375-50	BR-24-312	
	AT-12-276		BR-18-158	FT-18-440	BR-24-375	
	AT-12-276-50		BR-18-158-50	FT-18-440-50	BR-24-393	
	AT-12-375		BR-18-197	FT-18-500	BR-24-425	
	AT-12-375-50		BR-18-197-50	FT-18-500-50	BR-24-440	
	AT-12-440		BR-18-250	FT-24-197	BR-24-443	
	AT-12-440-50		BR-18-250-50	FT-24-197-50	BR-24-880	
	AT-18-062		BR-18-393	FT-24-250	PC-606	
	AT-18-062-50		BR-18-393-50	FT-24-250-50	PP-16-070	
	AT-18-087		BR-18-591-50	FT-24-276	PP-16-070-50	
	AT-18-087-50		BR-18-880-50	FT-24-276-50	PP-22-070	
	AT-18-105		BR-2300	FT-24-375	PP-22-070-50	
	AT-18-105-50		BR-24-070-50	FT-24-375-50	MED100.34	
	AT-18-118		BR-24-080-50	FT-24-440	MED100.35	
	AT-18-118-50		BR-24-098-50	FT-24-440-50	MED100.62	
	AT-18-125		BR-24-197-50	FT-24-500	MED100.59.1	
	AT-18-125-50		BR-24-200-50	FT-24-500-50	45906	
	AT-18-131		BR-24-236-50	H-FLEX001	45908	
	AT-18-131-50		BR-24-276-50	H-FLEX002	45910	
	AT-18-158		BR-24-312-50	H-FLEX003	45912	
	AT-18-158-50		BR-24-375-50	H-FLEX004	45914	
	AT-18-197		BR-24-393-50	H-FLEX005	96280	
	AT-18-197-50	BR-24-425-50	H-FLEX006	96280.0		
	AT-18-250	BR-24-440-50	H-FLEX007	96280.2		
	AT-18-250-50	BR-24-443-50	H-FLEX007A	96280.3		
	AT-18-276	BR-24-880-50	H-FLEX008H	96280.4		
	AT-18-276-50	BR-4199	H-FLEX009	96280.5		
AT-18-375	BR-4299	H-FLEX010	96280.6			
AT-18-375-50	BR-4399	H-FLEX021	96280.7			
AT-18-440	BR-4499	H-FLEX022	96280.8			
AT-18-440-50	BR-4599	H-FLEX023	96280.9			
AT-24-062						

Product Name	GMDN	Item Numbers				
Key Surgical Instrument and Channel Cleaning Brushes	34878 (Surgical instrument endoscope cleaning utensil, reusable)	AT-24-062-50	BR-4699	H-FLEX024	96281.3	
		AT-24-087	BR-4799	H-FLEX025	96281.4	
		AT-24-087-50	BR-4899	H-FLEX026	96281.7	
		AT-24-105	BR-4999	H-FLEX027	MED100.98	
		AT-24-105-50	BR-5099	H-FLEX033	26474	
		AT-24-118	BR-5199C	H-FLEX034	26475	
		AT-24-118-50	BR-6099	H-FLEX035	26476	
		AT-24-125	BR-8110	H-FLEXSAMP	26477	
		AT-24-125-50	BR-8110-50	MED100.10	26478	
		AT-24-131	BR-8115	MED100.11	26480	
		AT-24-131-50	BR-8115-50	MED100.12	26034	
		AT-24-158	BR-8210	MED100.13	26035	
		AT-24-158-50	BR-8210-50	MED100.14	26485	
		AT-24-197	BR-8310	MED100.15	09322	
		AT-24-197-50	BR-8310-50	MED100.16	09319	
		AT-24-250	BR-8315	MED100.17	09349	
		AT-24-250-50	BR-8315-50	MED100.18	09049	
	AT-24-276	BR-8410	MED100.19	09064		
	AT-24-276-50	BR-8410-50	MED100.20	09076		
	AT-24-375	BZ-06-2550	MED100.21	09095		
	AT-24-375-50	BZ-06-2550-50	MED100.22	09303		
	AT-24-440	BZ-08-125	MED100.23	09458		
	AT-24-440-50	BZ-08-125-50	MED100.24	09490		
	B-2100-50	BZ-10-050	MED100.25	09491		
	BBR001	BZ-10-050-50	MED100.26	09492		
	BBR002	BZ-12-062	MED100.27	BR-4120		
	BBR003	BZ-12-062-50	MED100.28	26029		
	BR-04-003	BZ-12-087	MED100.29	26486		
	BR-04-003-50	BZ-12-087-50	MED100.30	26487		
	BR-04-080	BZ-12-098	MED100.31	26488		
	BR-04-080-50	BZ-12-098-50	MED100.32			
	BR-06-039-50	BZ-12-125	MED100.48			
	BR-06-062	BZ-12-125-50	MED100.49			
	BR-06-062-50	BZ-12-158	MED100.52			
	BR-06-079	BZ-12-158-50	MED100.57			
	BR-06-079-50	BZ-16-250	MED100.58			
	BR-06-250	BZ-16-250-50	MED100.59			
	BR-06-250-50	BZ-18-062	MED100.61			
	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	S-2131	S-4000	09488
		D-2100BN-50	S-2131-50	N-3000	09489	
		D-2100SN	S-2300	N-2000	B-2100	
		D-2100SN-50	S-2300-50	26023	N-2121A	
		N-2100	UB-2100	26032	N-2121A-50	
		N-2100-50	UD-2100SN	09084	N-2200	
		N-2121	UN-2100	09459	N-2221	
		N-2121-50	UN-2100-50	09320	S-2121	
		N-2221-50	UN-2121-50	09478	N-2121A-50	
		N-2000-3	US-2100	26491	N-2200	

Product Name	GMDN	Item Numbers			
Key Surgical Toothbrush-Style Cleaning Brushes		N-3000-3 S-2100 S-2100-50 S-2121-50	US-2100-50 US-2300 N-3000A N-4000	26492 09485 09460 09325	N-2221 S-2121 79325
Key Surgical Endoscope Cleaning Brushes		26481 26305 09356 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-3308-50 BR-3309 BR-3309-50 BR-3310 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 BR-3711
Key Surgical Endoscope Cleaning Sponge	38835 (Surgical instrument endoscope cleaning utensil, single-use)	ES-50			