

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 (Surgical instrument endoscope cleaning utensil, single-use)	AT-12-062-50	BR-16-472	FT-12-250	PP-22-197
			AT-12-087	BR-16-472-50	FT-12-250-50	PP-24-250
			AT-12-087-50	BR-16-591	FT-12-276	PT-28-118
			AT-12-105	BR-16-591-50	FT-12-276-50	PT-28-197
			AT-12-105-50	BR-16-787	FT-12-375	FLEX008
			AT-12-118	BR-16-787-50	FT-12-375-50	FLEX009
		AT-12-118-50	BR-18-039	FT-12-440	FLEX025	
		AT-12-125	BR-18-039-50	FT-12-440-50	FLEX026	
		AT-12-125-50	BR-18-062	FT-12-500	BR-18-591	
		AT-12-131	BR-18-062-50	FT-12-500-50	BR-18-880	
		AT-12-131-50	BR-18-070	FT-18-197	BR-24-070	
		AT-12-158	BR-18-070-50	FT-18-197-50	BR-24-080	
		AT-12-158-50	BR-18-087	FT-18-250	BR-24-098	
		AT-12-197	BR-18-087-50	FT-18-250-50	BR-24-197	
		AT-12-197-50	BR-18-105	FT-18-276	BR-24-200	
		AT-12-250	BR-18-105-50	FT-18-276-50	BR-24-236	
		AT-12-250-50	BR-18-125	FT-18-375	BR-24-276	
		AT-12-276	BR-18-125-50	FT-18-375-50	BR-24-312	
		AT-12-276-50	BR-18-158	FT-18-440	BR-24-375	
		AT-12-375	BR-18-158-50	FT-18-440-50	BR-24-393	
		AT-12-375-50	BR-18-197	FT-18-500	BR-24-425	
		AT-12-440	BR-18-197-50	FT-18-500-50	BR-24-440	
		AT-12-440-50	BR-18-250	FT-24-197	BR-24-443	
		AT-18-062	BR-18-250-50	FT-24-197-50	BR-24-880	
		AT-18-062-50	BR-18-393	FT-24-250	PC-606	
		AT-18-087	BR-18-393-50	FT-24-250-50	PP-16-070	
		AT-18-087-50	BR-18-591-50	FT-24-276	PP-16-070-50	
		AT-18-105	BR-18-880-50	FT-24-276-50	PP-22-070	
		AT-18-105-50	BR-2300	FT-24-375	PP-22-070-50	
		AT-18-118	BR-24-070-50	FT-24-375-50	MED100.34	
		AT-18-118-50	BR-24-080-50	FT-24-440	MED100.35	
		AT-18-125	BR-24-098-50	FT-24-440-50	MED100.62	
		AT-18-125-50	BR-24-197-50	FT-24-500	MED100.59.1	
		AT-18-131	BR-24-200-50	FT-24-500-50	45906	
		AT-18-131-50	BR-24-236-50	H-FLEX001	45908	
		AT-18-158	BR-24-276-50	H-FLEX002	45910	
		AT-18-158-50	BR-24-312-50	H-FLEX003	45912	
		AT-18-197	BR-24-375-50	H-FLEX004	45914	
		AT-18-197-50	BR-24-393-50	H-FLEX005	96280	
		AT-18-250	BR-24-425-50	H-FLEX006	96280.0	
		AT-18-250-50	BR-24-440-50	H-FLEX007	96280.2	
		AT-18-276	BR-24-443-50	H-FLEX007A	96280.3	
		AT-18-276-50	BR-24-880-50	H-FLEX008H	96280.4	
		AT-18-375	BR-4199	H-FLEX009	96280.5	
	AT-18-375-50	BR-4299	H-FLEX010	96280.6		
	AT-18-440	BR-4399	H-FLEX021	96280.7		
	AT-18-440-50	BR-4499	H-FLEX022	96280.8		
	AT-24-062	BR-4599	H-FLEX023	96280.9		

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			