



Declaration of Conformity

We, the manufacturer,

Key Surgical LLC
 8101 Wallace Rd.
 Eden Prairie, MN 55344
 USA

ensure and declare with sole responsibility, that the following Class I non-sterile, non-measuring medical devices meet the provisions of the Council Directive 93/42/EEC (MDD) Annex VII for Medical Devices as amended by 2007/47/EC, which apply to them. These products also conform with the following applicable standards: EN ISO 13485:2016, ISO 14971:2007, EN ISO 14971:2012, and BS EN ISO 15223-1:2016. All supporting documentation is retained under the premises of the manufacturer.

Product Name	Item Number	UMDNS Code & Description
Key Surgical Burr Brushes	BR-1010, BR-1010-50, BR-1031, BR-1031-50, BR-1033, BR-1033-50, BR-1050	10-502: Brushes, Cleaning, Instrument, Burr
Key Surgical Instrument Cleaning Brushes	AT-18-062, AT-18-087, AT-18-105, AT-18-375, AT-18-440, BR-07-075, BR-07-075-50, BR-07-107, BR-07-107-50, BR-08-070, BR-100-32, BR-2400, BR-2450, BR-4200, BR-4300, BR-4310, BR-4320, BR-4330, BR-5099, AT-18-276, PP-16-087, PP-16-158, PP-18-197, PP-18-250, PP-18-393, PP-18-750, PP-22-039, PP-22-062, PP-22-087, PP-22-105, PP-22-125, PP-22-158, PP-24-250, PT-28-118, PT-28-197, PP-24-250-50, BZ-06-2550, BZ-08-125, BZ-10-050, BZ-12-062, BZ-12-087, BZ-12-098, BZ-12-125, BZ-12-158, BZ-16-250, BZ-18-062, BZ-18-079, BZ-18-1000, BZ-18-105, BZ-18-131, BZ-18-144, BZ-18-1543, BZ-18-158, BZ-18-197, BZ-18-236, BZ-18-250, BZ-18-312, BZ-18-354, BZ-18-393, BZ-18-433, BZ-18-472, BZ-24-125, BR-4140, BR-4120, PC-100C, PC-212C, PC-400P, PC-412P, PC-400, PC-100, PC-200C, PC-300P, PC-312P, PC-515, PC-512, PC-503, PC-606, S-2121, S-2121-50, S-2131, S-2131-50, S-2300, S-2300-50, BR-31-118, BR-31-197, BR-31-276, BR-04-003, BR-04-003-50, S-4000, BR-3044, BR-3047, BR-3300, BR-3305 BR-4000, BR-4199, BR-4299, BR-4399, BR-4499, BR-4599, N-3000, N-4000	21-134: Brushes, Cleaning
Key Surgical Specialty Cleaning Brushes	BR-075-18, BR-075-24, BR-075-32, BR-075-42, BR-075-99, BR-100-18, BR-100-24, BR-100-42, BR-100-42-50, BR-100-99, BR-150-18, BR-150-24, BR-150-32, 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-4799, BR-4899, BR-4699, BR-3711-100, BR-3711-50, BR-3799-50, BR-3030, BR-3030-50, BR-3035, BR-3035-50, BR-3040, BR-3040-50, BR-3044, BR-3047, BR-3201, BR-3202, BR-3300, BR-3305, BR-3308, 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-3410, BR-3410-50, BR-3420, BR-3420-50, N-2000-3	
Key Surgical Endoscope Cleaning Sponge	ES-50	
Key Surgical Channel Cleaning Brushes	AT-18-118, AT-18-118-50, AT-18-125, AT-18-131, AT-18-158, AT-18-197, AT-18-250, AT-24-125-50, B-2100, BR-06-039, BR-06-039-50, BR-06-062, BR-06-062-50, BR-06-079, BR-06-079-50, BR-06-250, BR-06-375, BR-06-500, 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-	

Product Name	Item Number	UMDNS Code & Description
	092, BR-08-105, BR-08-118, BR-08-118-50, BR-08-131, BR-08-131-50, BR-08-144, 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-12-079, BR-12-079-50, BR-12-118, BR-12-118-50, BR-12-158, BR-12-158-50, BR-12-197, BR-12-236, BR-16-197, BR-16-197-50, BR-16-236-50, BR-16-276, BR-16-276-50, BR-16-393, BR-16-393-50, BR-16-443, BR-16-443-50, BR-16-472, BR-16-591, BR-16-787, BR-16-787-50, BR-18-039, BR-18-039-50, BR-18-062, BR-18-062-50, BR-18-070, BR-18-070-50, BR-18-087, BR-18-087-50, BR-18-105, BR-18-105-50, BR-18-125, BR-18-125-50, BR-18-158, BR-18-158-50, BR-18-197, BR-18-197-50, BR-18-250, BR-18-393, BR-18-393-50, BR-18-591, BR-18-591-50, BR-18-880, BR-2300, BR-24-070, BR-24-070-50, BR-24-080, BR-24-098, BR-24-197, BR-24-197-50, BR-24-200, BR-24-200-50, BR-24-236, BR-24-236-50, BR-24-276, BR-24-276-50, BR-24-312, BR-24-312-50, BR-24-375, BR-24-375-50, BR-24-393, BR-24-393-50, BR-24-425, BR-24-425-50, BR-24-440, BR-24-440-50, BR-24-443, BR-24-880, BR-8110, BR-8115, BR-8115-50, BR-8210, BR-8310, BR-8315, BR-8315-50, BR-8410, BR-8410-50, BZ-06-2550, BZ-08-125, BZ-10-050, BZ-12-062, BZ-12-087, BZ-12-098, BZ-12-125, BZ-12-158, BZ-16-250, BZ-18-062, BZ-18-079, BZ-18-1000, BZ-18-105, BZ-18-131-50, BZ-18-144, BZ-18-1543, BZ-18-158, BZ-18-197, BZ-18-236, BZ-18-250, BZ-18-312, BZ-18-354, BZ-18-393, BZ-18-433, BZ-18-472, BZ-24-125, BZ-24-125-50, FT-12-197-50, FT-12-250, FT-12-276, FT-12-375, FT-12-440, FT-12-500, FT-12-500-50, FT-18-197, FT-18-197-50, FT-18-250, FT-18-276, FT-18-375, FT-18-440, FT-18-440-50, FT-18-500, FT-18-500-50, FT-24-197, FT-24-197-50, FT-24-250, FT-24-250-50, FT-24-276, FT-24-276-50, FT-24-375, FT-24-440, FT-24-440-50, FT-24-500, FT-24-500-50, PC-100C, PC-112C, PC-200C, PC-212C, PC-300P, PC-312P, PC-400P, PC-412P, PC-503, PP-16-039, PP-16-062, PP-16-087, PP-16-087-50, PP-16-105, PP-16-125, PP-16-158, PP-22-062, PP-22-197, BR-3045	
Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN, D-2100SN, N-2100, N-2121, S-2100, S-2100-50, S-2131	
Endoscope Bedside Kit	26496	33-294 Sponges, Multipurpose
Key Surgical Biopsy Valves (non-sterile)	26050, 26053	16-155: Endoscope biopsy valve
Key Surgical Cannulas (non-sterile)	05001, 05003, 05005, 05007, 05009	15-206: Wound Irrigation Cannula
Key Surgical Instrument Tip Caps	3-01-01, 3-01-02, 3-01-03, 3-01-04 3-01-05, 3-01-06 3-01-07, 3-01-08, 3-01-09, 3-02-01, 3-02-02, 3-02-03 3-02-04, 3-02-05, 3-02-06, 3-02-07, 3-02-08, 3-02-09, 3-03-01, 3-03-02, 3-03-03, 3-03-04, 3-03-05, 3-03-06, 3-03-07, 3-03-08, 3-03-09, 3-03-11, 3-03-12, 3-03-13, 303-15, 3-04-01, 3-04-02, 3-04-03, 3-04-05, 3-04-06, 3-04-07, 3-04-08, 3-04-09, 3-04-11, 3-04-12, 3-04-13, 3-04-15, 3-04-17, 3-04-18, 3-04-19, 3-04-99, 3-05-02, 3-	16-222: Protective Tips, Surgical Instrument


Product Name	Item Number	UMDNS Code & Description
	05-06, 3-05-07, 3-05-25, 3-05-23, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-06-01, 3-06-02, 3-06-03, 3-06-04, 3-06-05, 3-06-07, 3-06-50, 3-07-03, 3-07-05, 3-07-09, 3-08-01, 3-08-02, 3-08-03, 3-08-04, 3-08-05, 3-08-06, 3-08-07, 3-08-08, 3-08-09, 3-08-10, 3-08-11, 3-08-12, 3-08-13, 3-08-15, 3-08-17, 3-08-18, 3-08-19, 3-09-03, 3-09-04, 3-09-05, 3-09-07, 3-09-08, 3-09-09, 3-09-10, 3-10-01, 3-10-02, 3-10-03, 3-10-05, 3-11-01, 3-11-02, 3-11-03, 3-11-04, 3-11-05, 3-11-06, 3-11-07, 3-11-08, 3-11-09, 3-12-01, 3-12-02, 3-12-03, 3-12-04, 3-12-05, 3-12-06, 3-12-07, 3-12-08, 3-12-09, 3-13-03, 3-13-04, 3-13-05, 3-13-07, 3-14-03, 3-14-05, 3-14-07, 3-15-01, 3-15-02, 3-15-03, 3-15-04, 3-15-05, 3-15-06, 3-15-07, 3-15-08, 3-15-09, 3-16-05, 3-16-06, 3-16-07, 3-16-08, 3-16-09, 3-60-01, 3-60-02, 3-60-03, 3-60-04, 3-60-05, 3-60-06, 3-60-07, 3-60-08, 3-60-09, 3-60-10, 3-60-11,	
Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS	
Key Surgical Instrument Sleeves	CS-1010W, CS-2025W, CS-3050W	
Key Surgical Endoscope Tip Protector	EN-900	
Finger Mat	FM-1810	
Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB	
Key Surgical Mesh Trays	MT-5500, RMT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-9001, MT-9101, MT-9521, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9110, MT-9200, MT-9210, MT-9101, MT-9521	12-143: Instrument Tray
Key Surgical Scope Baskets	SB-1210, SB-4210, SB-4610, SB-6520	
Key Surgical Tray Corner Protectors	CS-9113, CS-9125C	15-907: Corner Protectors
Key Surgical Adhesive Remover	MJ-7004, MJ-7032	10-033: Adhesive Removers
Key Surgical Face & Select Shields	4504, 4509, 4600, 4615, 4625, 4610, 4620	11-961: Shields, Splash, Face
Key Surgical Bite Blocks	EN-210, EN-300, EN-310, EN-315, EN-320	10-405: Bite Blocks

We hereby appoint Medical Device Safety Service (MDSS)
 Schiffgraben 41
 D-30175 Hannover
 Germany

as the European Authorized Representative as defined in Article 1(j) of the MDD.

Conformity Assessment Route: Annex VII

Issued By:

Signature:  **Date:** 12/03/2019

Name: Kasey Koenig

Position: Director, Global Quality and Regulatory