

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 IIa medical devices and Class I Sterile medical devices meet the provisions of the Council Directive 93/42/EEC (MDD) Annex V for Medical Devices as amended by 2007/47/EC, which apply to them. These products also conform with the following applicable regulations: 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	Product Class	Rule (Per MDD)
Key Surgical Cannulas	05000, 05000-10, 05002, 05004, 05006, 05008, 05021, 05022, 05023, 05026, 05028, 05050, 05052, 05053, 05056, 05058	15-206: Wound Irrigation Cannula	Class I Sterile	1
Key Surgical Cautery Tip Cleaner	TC-200	15-013: Cleaners	Class I Sterile	1
Key Surgical Electro Lube	EL-101	15772: Lubricants, Instrument	Class IIa Sterile	6
Key Surgical K-Wire and Pin Covers	C-028, C-035, C-045, C-054, C-062, C-078, C-093, C-109, C-125, C-141, C-156, C-188	16-222: Protective Tips, Surgical Instrument	Class I Sterile	1
Key Surgical Silicone Clamp Covers (sterile and non-sterile)	(Sterile): VS-101, VS-102, VS-103 (Non-Sterile): VS-201, VS-202, VS-203, VS-201-100, VS-202-100, VS-203-100	15-778: Covers, Clamp	Class IIa	7
Key Surgical Skin Markers	SM-100, SM-200, SM-300	12-443: Markers, Skin	Class I Sterile	1
Key Surgical Suture Booties	VB-1100, VB-1105, VB-1110, VB-1115, VB-1120, VB-1215, VB-1315, VB-2000	16-222: Protective Tips, Surgical Instrument	Class IIa	7
Key Surgical Vascular Loops	VL-201, VL-202, VL-203, VL-204, VL-205, VL-206, VL-207, VL-208, VL-214, VL-215, VL-218	12-397: Loops, Vascular	Class IIa	7

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 V
Certificate issued by: BSI Group the Netherlands B.V. (2797)
Certificate No.: CE 666820

Issued By:

Signature:  **Date:** 2021-07-19

Name: Coletta Cohara

Position: Director Quality and Regulatory Compliance