

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	UMDNS Description	UMDNS Code	Product Class	Rule (Per MDD)
Key Surgical Cannulas	Wound Irrigation Cannula	15-206	Class I Sterile	1
Key Surgical Cautery Tip Cleaners	Cleaners	15-013	Class I Sterile	1
Key Surgical K-Wire and Pin Covers	Protective Tips, Surgical Instrument	16-222	Class I Sterile	1
Key Surgical Light Handle Covers	Covers	15-571	Class I Sterile	1
Key Surgical Silicone Clamp Covers (sterile and non-sterile)	Covers, Clamp	15-778	Class IIa	7
Key Surgical Skin Markers	Markers, Skin	12-443	Class I Sterile	1
Key Surgical Vascular Booties	Protective Tips, Surgical Instrument	16-222	Class IIa	7
Key Surgical Vascular Loops	Loops, Vascular	12-397	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: October 25, 2019

Name: Kasey Koenig
Position: Director, Global Quality, Regulatory and DPO