

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: **K-Wires & Pin Covers**
(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:

A handwritten signature in blue ink, appearing to read 'Steve Deline'.

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 K-Wires & Pin Covers	63247 (Surgical instrument guard, single-use, 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