

## 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:** **Chirol Ultra**  
(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 US

#### 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
ChiroI Ultra	63385 (Medical device cleaning agent)	02110