

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: **Container Filters**
(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:



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			
Container Filters	60909 (Sterilization container filter)	01140	01300	01363	26515
		01141	01304	01365	27325
		01142	01306	01366	27335
		01143	01312	01367	27345
		01144	01314	01368	27355
		01145	01315	01369	27365
		01148	01317	01373	91140
		01149	01318	04111	26510
		01152	01319	1070020	ME01194
		01153	01321	26510	ME26515
		01157	01322	27320	ME27325
		01158	01323	27330	ME27335
		01167	01327	27340	ME27345
		01168	01330	27350	ME27355
		01181	01331	27360	ME27365
		01183	01332	55-291-01-04	01149MED
		01186	01346	61140	01181MED
		01188	01347	71140	01186MED
		01189	01348	71141	01141MED
		01194	01350	71194	01183MED
01196	01355	91140	01305		
01198	01356				