

## EC Declaration of Conformity

We, Intersurgical Ltd (address: Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, United Kingdom) as manufacturer, hereby declare under the sole responsibility of that the below mentioned devices comply with European Medical Devices Directive 93/42/EEC with all amendments and transposing legislation.

Authorised Representative in the European Economic Area (EEA):  
UAB Intersurgical (address: Arnioniu g. 60, Pabradė, LT-18170, Lithuania)

### Filters

**These are class IIa devices in accordance with rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC** (classification.doc)

GMDN code – 60837, 63171, 63459, 61097, 60506

Essential requirements checklist is on IQR139.

Internally manufactured components master data is on EFACS (Parts Master) and design drawings are on IQR69 (Product and Mould Drawing List).

Internally manufactured finished products master data, production drawings and Master Product Formulae are on EFACS (Master Product Formula, Parts Master) and IQR69 (Product and Mould Drawing List).

Externally manufactured materials, components, design drawings and products are on EFACS (Parts Master), IQR98 (Incoming Product Specification) and IQR69 (Product and Mould Drawing List).

Instructions for use, pack inserts and labels are as detailed on EFACS (Master Product Formula) and IQR107 (Index of Controlled Artworks).

Label content is on EFACS (Master Product Formula) and Labels Printing System.

Product realisation processes are referenced in IQM section 7.1

### Product Codes

As listed in EFACS MPF Details under group DCFILTER.DOC.

This range is subject to the procedure set out in Annex 2 excluding section 4 of Directive 93/42/EEC as amended by 2007/47/EC, under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House Noorderlaan 87-2030, Antwerpen, Belgium

EC Certificate Full Quality Assurance System GB19/964232 has been issued for the management system of Intersurgical Ltd, which has been assessed and certified according to the requirements of Annex 2 excluding section 4 of Directive 93/42/EEC as amended by 2007/47/EC.



Ivan Seniut  
Group Quality and Regulatory Affairs Director  
Duly authorised for and on behalf of Intersurgical Ltd  
Crane House, Molly Millars Lane, Wokingham,  
Berkshire, RG41 2RZ, United Kingdom

Issue 21  
Valid from 7 April 2022  
DCFILTER.DOC

**Appendix for EU Declaration of Conformity Group: DCFILTER.DOC**

Product Codes:

1344000S	1344002S	1344007S	1344009S	1344010S
1344011S	1344012S	1344131	1344351S	1344711S
1544000	1544007	1544011	1544012	1544197
1544351	1544707	1545000	1545020	1644000
1644007	1644011	1644012	1644035	1644137
1690000	1690000S	1690001	1690002	1690003
1690007	1691000	1691001	1691002	1691003
1691004	1691005	1691006	1691007	1691008
1691009	1691010	1691011	1691012	1691013
1691014	1691015	1691016	1691017	1691020
1691050	1691051	1691052	1691053	1691063
1691064	1691065	1691090	1691091	1691092
1691094	1744000S	1744002S	1744011S	1744580S
1745000	1745011	1745012	1745015	1745136
1745180	1745197	1745351	1745352	1745711
1788000	1790000	1790000S	1790007	1944000
1944003	1944003S	1944007S	1944011	1944700
2715000	4708000	5361000		