

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, 60839, 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 19
Valid from 1 January 2021
DCFILTER.DOC

**Intersurgical EC Declaration of Conformity Groups (DC Group) Report
Showing product codes covered by each Declaration of Conformity**

December, 2020

EC Declaration of Conformity Group: DCFILTER.DOC

DOC 10

Products:

1344000S	1344002S	1344007S	1344009S	1344010S
INTER-GUARD BREATHING FILTER WITH LUER PORT - STERILE	INTER-GUARD B/FILTER, S/SET CATHETER MOUNT, DETACHABLE ELBOW	INTER-GUARD FILTER - STERILE	INTER-GUARD BREATHING FILTER WITHOUT LUER PORT	INTER-GUARD BREATHING FILTER WITH LUER PORT
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1344011S	1344012S	1344131	1344351S	1344711S
INTER-GUARD B/FILTER, LUER PORT, SUPERSET CATHETER MOUNT	INTER-GUARD BREATHING FILTER, LUER PORT, SUPERSET CATH MNT	INTER-GUARD FILTER M/PIECE	INTER-GUARD+, LUER PORT, FLEXIBLE CATHETER MOUNT	INTER-GUARD FILTER SUPERSET CATHETER MOUNT
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1544000	1544007	1544011	1544012	1544197
CLEAR-GUARD 3 FILTER	CLEAR-GUARD 3 FILTER	CLEAR-GUARD 3 FILTER + SUPERSET	CLEAR-GUARD 3 FILTER L/PORT SS/CM ELBOW	CLEAR-GUARD 3 FILTER L/PORT ELBOW
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1544351	1544707	1545000	1644000	1644007
CLEAR-GUARD 3 FILTER PORT, FLEXIBLE C/MOUNT FIXED ELBOW	CLEAR-GUARD 3 FILTER 22F/15M-22M/15F	CLEAR-GUARD 3 ANG FILTER L/PORT 22F/15M-22M/15F	CLEAR-GUARD MIDI LV FILTER L/PORT	CLEAR-GUARD MIDI LV FILTER 22F-22M/15F
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1644011	1644012	1644035	1644137	1690000
CLEAR-GUARD MIDI LV FILTER L/PORT SUPERSET CATHETER MOUNT	CLEAR-GUARD MIDI LV FILTER L/PORT SUPERSET C/MOUNT, ELBOW	CLEAR-GUARD MIDI LV FILTER L/PORT SS/CM 22F/15M-22M/15F	CLEAR-GUARD MIDI LV FILTER M/PIECE	FLO-GUARD FILTER
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1690000S	1690001	1690002	1690007	1690030
FLO-GUARD FILTER	FLO-GUARD FILTER 22F-22M	FLO-GUARD FILTER	FLO-GUARD BREATHING FILTER	FLO-GUARD FILTER 22F-22M
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1691000	1691001	1691002	1691003	1691004
PULMO-PROTECT LF FILTER	PULMO-PROTECT LF FILTER	PULMO-PROTECT FILTER	PULMO-PROTECT LF FILTER	PULMO-PROTECT LF FILTER INTEGRATED M/PIECE
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1691005	1691006	1691007	1691008	1691009
PULMO-PROTECT LF FILTER INTEGRATED M/PIECE	PULMO-PROTECT LF FILTER INTEGRATED M/PIECE	PULMO-PROTECT LF FILTER INTEGRATED M/PIECE	PULMO-PROTECT LF FILTER INTEGRATED M/PIECE NOSE CLIP	PULMO-PROTECT LF FILTER INTEGRATED M/PIECE NOSE CLIP
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1691010	1691011	1691012	1691013	1691014

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PULMO-PROTECT LUNG FUNCTION FILTER,FLEX MOUTHPIECE &NOSECLIP	PULMO-PROTECT LF FILTER	PULMO-PROTECT LF FILTER	PULMO-PROTECT FILTER FLEXIBLE MOUTHPIECE AND N/CLIP	PULMO-PROTECT FILTER FLEXIBLE MOUTHPIECE AND N/CLIP
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1691015	1691016	1691020	1691050	1691051
PULMO-PROTECT FILTER FLEXIBLE MOUTHPIECE AND N/CLIP	PULMO-PROTECT,PULMONARY FUNCTION FILTER,MOUTHPIECE ,NOSE CLIP	FLEXIBLE MOUTHPIECE	PULMO-PROTECT LF FILTER	PULMO-PROTECT LF FILTER
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1691052	1691063	1691064	1691065	1744000S
PULMO-PROTECT LF FILTER	PULMO-PROTECT FILTER N/CLIP	PULMO-PROTECT FILTER N/CLIP	PULMO-PROTECT LF FILTER N/CLIP	HYDRO-GUARD MINI FILTER
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1744002S	1744011S	1744580S	1745000	1745011
HYDRO-GUARD MINI BREATHING FILTER	HYDRO-GUARD MINI BREATHING FILTER, SUPERSET CATHETER MNT	HYDRO-GUARD MINI BREATHING FILTER WITH LUER PORT, CATH MNT	HYDRO-GUARD MINI FILTER	HYDRO-GUARD MINI FILTER SUPERSET CATHETER MOUNT
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1745012	1745015	1745136	1745180	1745197
HYDRO-GUARD MINI FILTER SUPERSET CATHETER MOUNT, ELBOW	HYDRO-GUARD MINI B/FILTER,SUPERSET CATHETER MOUNT & SWVL ELB	HYDRO-GUARD MINI FILTER SUPERSET CATHETER MOUNT	HYDRO-GUARD MINI FILTER L/PORT SMB/CM D/B SWVL ELB FTC	HYDRO-GUARD MINI FILTER ELBOW
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1745351	1745352	1745711	1788000	1790000
HYDRO-GUARD MINI FILTER L/PORT FLEX/CM ELBOW	HYDRO-GUARD MINI FILTER SUPERSET CATHETER MOUNT	HYDRO-GUARD MINI FILTER SUPERSET CATHETER MOUNT, DET ELBOW	AIR-GUARDFILTER	AIR-GUARD CLEAR FILTER
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1790000S	1790007	1944000	1944003	1944003S
AIR-GUARD	AIR-GUARD CLEAR 7 FILTER	FILTA-GUARD BREATHING FILTER	FILTA-GUARD FILTER L/PORT	FILTA-GUARD FILTER L/PORT 22F-22M/15F
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS
1944007S	1944011	1944700	2715000	4708000
FILTA-GUARD BREATHING FILTER	FILTA-GUARD FILTER L/PORT SUPERSET CATHETER MOUNT	CLEAR-GUARD FILTER 22F-22M/15F	MONITORING LINE HYDROPHOBIC FILTER, LUER LOCK CONNECTIONS	NFLOW SILENCER KIT WITH CLEAR GUARD
BREATHING FILTERS	BREATHING FILTERS	BREATHING FILTERS	ANAESTHETIC SYSTEMS	CRITICAL CARE
5361000				

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Products:

1544150				
CLEAR-GUARD 3 BREATHING FILTER				
BREATHING FILTERS				

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Products:

FILTER AND MONITOR LINE FOR BILEVEL BREATHING SYSTEMS				
ANAESTHETIC SYSTEMS				