

2154000

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)

Anaesthetic Breathing Systems

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

GMDN codes - 37704, 37021

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 DCABS.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 23
Valid from 03 May 2021
DCABS.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: DCABS.DOC

DOC 1

Products:

2150160S	2151000	2151000S	2151001	2151003
22mm COMPACTB/S 3L/B HMEF >= 1.5M	22mm COMPACT B/S LUER/ELB >= 2.0m	22mm COMPACTB/S LUER/ELB >= 2m	COMPACT, EXTENDABLE BREATHING SYSTEM WITH SAFETY CAP	22mm COMPACT B/S LUER/ELB >= 2m
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
2151008	2151010	2151020	2151161S	2151800
22mm COMPACT B/S 2L/B LUER/ELB >= 2m	COMPACT II ADJUSTABLE BREATHING SYSTEM, LUER ELBOW, 2M	22mm COMPACT B/S 2L/B LUER/ELB >= 2m	22mm COMPACTB/S 3L/B HMEF >= 2M	22mm COMPACT B/S LUER/ELB >= 2m
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
2152000	2152011	2153000	2153004	2153005
22mm COMPACT B/S 3L/B LUER/ELB LIMB >= 2m	COMPACT, EXTENDABLE BREATHING SYSTEM WITH 3L BAG, SAFETY CAP	22mm COMPACT B/S 3L/B LUER/ELB F LIMB >= 2m	22mm COMPACT B/S 2L/B LUER/ELB F LIMB >= 2m	22mm COMPACT BREATHING SYSTEM, 3L BAG AND FILTER
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
2154000	2154000S	2154002	2154006	2154014
22mm COMPACT B/S 2L/B LUER/ELB LIMB >= 2m	22mm COMPACT B/S 2L/B LUER/ELB LIMB >= 2m	22mm COMPACT B/S 2L/B LUER/ELB LIMB >= 2m	22mm COMPACT B/S 2L/B LUER/ELB SWVL/Y LIMB >= 2m	22mm COMPACT B/S 2L/B LUER/ELB LIMB >= 2m
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
2154017	2154022	2154023	2155000	2155001
22mm COMPACT B/S 2L/B LUER/ELB M/LINE F LIMB >= 2m	22mm COMPACT B/S 2L/B LUER/ELB HMEF (5) LIMB >= 2m	22mm COMPACT, 2L BAG, 1.5M LIMB, 2 FILTERS, MON LINE, 2.0M	22mm COMPACT B/S P/Y W/TRAPS LIMB >= 3m	22mm COMPACT B/S 2L/B P/Y W/TRAPS LIMB >= 3m
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
2155003	2155006	2156000	2156003	2156004
22mm COMPACT B/S 2L/B ELB W/TRAPS LIMB >= 3m	22mm COMPACT B/S W/TRAPS >= 3m	22mm COMPACT B/S 2L/B LUER/ELB BAG LIMB >= 3.0m	22mm COMPACT B/S 2L/B LUER/ELB M/LINE >= 3m	22mm COMPACT B/S 2L/B LUER/ELB F LIMB >= 3m
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
2156005	2156006	2156008	2157000	2157001
22mm COMPACT B/S 3L/B LUER/ELB F LIMB >= 3m	22mm COMPACT B/S 2L/B LUER/ELB M/LINE ANAFM LIMB >= 3m	22mm COMPACT, 2L BAG, 1.5M LIMB, 2 FILTERS, MON LINE, 3M	22mm COMPACT B/S 2L/B LUER/ELB BAG LIMB >= 3.0m	22mm COMPACT B/S LUER/ELB DETACH/Y >= 3m
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
2157004	2157007	2157008	2158000	2158007