

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 31

Valid from 20 September 2024

DCABS.DOC

Appendix for Declaration of Conformity Group: DCABS.DOC

Product Codes:

2126004	2140000	2141000	2141001	2141004
2141009	2142000	2142002	2142003	2142005
2142007	2142010	2142014	2142015	2142016
2142017	2142024	2142026	2142027	2142028
2142029	2142030	2142034	2142035	2142040
2142044	2142045	2142048	2142049	2142050
2142051	2142052	2142053	2142058	2142062
2142082	2142083	2142085	2142086	2142091
2143000	2143001	2143002	2143017	2144000
2145000	2145001	2150000	2150001	2150160S
2151000	2151000S	2151001	2151003	2151020
2151161S	2151800	2152000	2152011	2153000
2153007	2154000	2154000S	2154006	2154017
2154023	2155000	2155001	2155003	2155006
2155009	2156000	2156003	2156004	2156005
2156006	2156007	2156008	2157000	2157001
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2164002	2165000	2165001	2165002	2165006
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2620023	2630001	2820006s	2900000	2900000S
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2900020	2900021	2900023	2900025	2900027
2900039	2900040	2900042	2900047	2900050
2900051	2900052	2900055	2900058	2900062
2900066	2900071	2900075	2900076	2900079
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2901007	2901008	2901009	2901011	2901012
2901013	2901017	2901018	2901021	2902000
2902000S	2902001	2902002	2902005	2902012
2902014	2902015	2902016	2902017	2902018

2902019	2902021	2902022	2902026	2902028
2903000	2903001	2903003	2903004	2903005
2903005S	2903006	2903007	2903008	2903010
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2920000	2920001	2920010	2920011	2920300
2920301	2920310	2920311	4000003	4050020
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5007011	5007012	5008006	5008009	5008019
5009007	5009011	5009019S	5009022	5009025S
5009026S	5009039	5009041	5009044	5009058
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5011008S	5015004	5015005	5016001	5016005
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5017002	5017005	5154000S	5202001	5209002
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5512009	5512012	6089000	6202002	6202005
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2108046	2108048S	2108050	2108052S	2110000
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2112012	2115000	2115009	2115011	2115013
2115015	2116000	2117000	2119001	2119002
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2121005	2121011	2121014	2121019	2121024
2121035	2121042	2121043	2121045	2121047
2121048	2121052	2121053	2122000	2122007
2122010	2122011	2122012	2122017	2122019
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