

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)

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: 37706, 37705, 36849

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 DCBS.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 17

Valid from 31 January 2023

DCBS.DOC

Appendix for EU Declaration of Conformity Group: DCBS.DOC

Product Codes:

1415000	1415002	1416000	2000000	2000000S
2000006	2000017	2000019	2000020	2000029
2000052	2000058	2000068	2000078	2000098
2000099	2000204	2000206	2000213	2000214
2000222	2000253	2001000	2001000S	2002000
2002021	2003000	2004000	2004017	2005001
2006000	2006002	2007002	2007003	2007004
2009000	2009000S	2009020	2009029	2009032
2009033	2009059	2009070	2009074	2009077
2009080	2009095	2009096	2009097	2009206
2009221	2009231	2020001	2030015	2030016
2034000	2036001	2036060	2036067	2036068
2036070	2036072	2036073	2036075	2070000
2072000	2073000	2074000	2075000	2076000
2077000	2080000	2080004	2080008	2082000
2083003	2083004	2143005	2143006	2200000
2209000	2209001	2230000	2232000	2232001
2232002	2234000	2234001	2236002	2236005
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4010000	4010001	4050000	4050002	4050004
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4054000	4105006	4105007	4105009	4500000
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4609007	4650000	4651000	4652000	4700015
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5000030S	5000032S	5000033	5000034	5000059
5000060	5000065	5000190	5001000	5001000S

5001005	5001006	5001007	5001009	5001010
5001011	5001012	5003000	5004000	5004002
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5007006	5008000	5008001	5008002	5008003
5008004	5008020	5009000	5009000S	5009001
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5009009	5009033S	5009034S	5009037S	5009043
5009190	5010000	5010005S	5010010S	5012000
5013005	5013018	5013019	5013022	5015000
5016000	5018000	5018000S	5018003	5018011
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6430005	6431000	6431002	6431009	6431011
6431012	6432000	6432001	6432002	6432005
6433000	RM21301	RM21302	RM21303	RM21304
RM21305	RM21306	RM21308	RM21309	RM21311
RM21312	RM21313	RM21314	RM21321	RM21322
RM21324	RM21325			