INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 9656 300 F: +44 (0)118 9656 356
info@intersurgical.com www.intersurgical.com

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)

HMEF's
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 – 46816, 61134
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 DCHMEF.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
DCHMEF.DOC

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

April, 2021

EC Declaration of Conformity Group: DCHMEF.DOC **DOC 15**

Products:

1331000S	1331006S	1331007S	1331197S	1332000S
1332001S	1341000S	1341003S	1341004S	1341005S
1341006S	1341007S	1341008S	1341011S	1341012S
1341016S	1341197S	1341211S	1341351S	1341580S
1341777	1341974S	1441000	1441001S	1441197
1541000	1541007	1541011	1541012	1541013
1541015	1541019	1541020	1541060	1541197
1541351	1541974	1541975	1542000	1641000
1641012	1641014	1641197	1831000	1831011
1831197	1906000	1941000	1941001	1941011
1941012	1941015	1941021	1941060	1941120
1941196	1941197	1941199	1941351	1942000
1942011				