



Quality, innovation and choice

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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.

Nebulisers, Cirrus, Micro-Cirrus and HOT Top

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 code - 31309

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 IQR139 (Checklist of Controlled Documents).

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 DCNEB.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 0120, SGS United Kingdom Ltd, Unit 202B, Worle Parkway, Worle Weston Super Mare, Somerset, BS22 6WA, United Kingdom.



Ivan Seniut
Group Quality and Regulatory Affairs Director
Duly authorised for and on behalf of Intersurgical Ltd
Crane House, Molly Millars Lane, Wokingham,
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DCNEB.DOC

UK • Ireland • France • Germany • Spain • Portugal • Italy
Netherlands • Sweden • Lithuania • Russia • Czech Republic
South Africa • China • Japan • Taiwan • Philippines
USA • Colombia • Australia

Intersurgical Limited Registered in England No. 1488409
Directors S. K. Williams • H. Bellm • K. Jacob • D. Williams • M. Hinton

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

February, 2018

EC Declaration of Conformity Group: DCNEB.DOC

DOC 26

Products:

1103005	1103008	1200001	1200051	1402000
1402003	1402004	1414000	1415000	1415002
1416000	1417000	1417110	1418000	1444000
1453000	1453001	1453003	1453005	1453007
1453010	1453013	1453015	1453017	1453018
1453025	1454000	1454010	1454013	1454015
1454016	1454018	1455000	1463013	1463015
1463815	1464000	1464004	1464005	1464006
1464008	1464009	1464011	1464021	1464022
1464023	1468013	1468015	1471015	1472015
1473015	1474015	1475013	1475015	1477002
1477003	1478013	1478015	1484130	1485000
1486000	1493000	1493001	1493004	1494000
1494001	1495000	1496001	1497000	1497002

1497001	1495000	1490001	1497000	1497002
1501000	1501002	1501003	1501005	1503000
1503130	1508001	1510000	1814000	1953001
1958000	2083003	2505000	2505901	2506000
2507000	2507001	2507002	2509000	2605000
2605001	2606000	2608000	2609000	2609003
2609013				