

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 Masks

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 – 46232, 35176

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 DCAMSK.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 10
Valid from 1 January 2021
DCAMSK.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: DCAMSK.DOC

DOC 3

Products:

1120000	1120111	1121000	1121111	1122000
1122111	1123000	1123002	1123003	1123111
1124000	1124002	1124003	1124111	1125000
1125002	1125003	1125111	1126000	1126003
1126111	1127000	1127001	1127111	1128000
1128001	1128111	1129000	1129001	1129111
1220000	1221000	1222000	1223000	1224000
1225000	1226000	1511000	1511111	1512000
1512111	1513000	1513001	1513111	1514000
1514008	1514111	1515000	1515003	1515007
1515009	1515010	1515012	1515111	1516000
1516004	1516011	1516111	1517000	1517111
1591000	1592000	1593000	1594000	1641015
7089000	7090000	7093000	7191000	7192000
7193000	7194000	7290000	7291000	7292000
7292001	7293000	7293001	7293002	7293003
7294000	7294001	7294002	7294003	7295000
7295001	7295002	7295003	7296000	7296001
8100000	8110000	8111000	8112000	8724013
8748006	8748011	8748012	8748013	8748014
8749000	8749001	8749002	8749003	8749004
8749005	8749006	8820000	8821000	8822000
8823000	8824000	8825000	8826000	8848000
8848001	8848002	8848003	8848004	8848005
8848006	8920000	8921000	8922000	8923000
8924000	8925000	8926000		