

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.

I-gel Supraglottic Airways

These are class IIA medical devices, in accordance with rule 5 of Annex IX of the Medical Devices Directive 93/42/EEC (classification.doc)

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 DCIGEL.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 7 February 2020
DCIGEL.DOC

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

September, 2019

EC Declaration of Conformity Group: DCIGEL.DOC

DOC 19

Products:

8201000	8202000	8203000	8204000	8205000
I-GEL SUPRAGLOTTIC AIRWAY, SIZE 1.0, NEONATE, 2-5KG	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 2.0, SMALL PAEDIATRIC	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 3, SMALL ADULT, 30- 60KG	I-GEL, MEDIUM ADULT, SUPRAGLOTTIC AIRWAY, SIZE 4 (50- 90KG)	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 5, LARGE ADULT, 90+KG
I-GEL	I-GEL	I-GEL	I-GEL	I-GEL
8215000	8225000	8604000	8703000	8703030
I-GEL SUPRAGLOTTIC AIRWAY, SIZE 1.5, INFANT, 5-12KG	I-GEL SUPRAGLOTTIC AIRWAY, SIZE 2.5	I-GEL PLUS,MEDIUM ADULT,SUPRAGLOTT IC AIRWAY,SIZE 4 (50 -90KG)	I-GEL O2 RESUS PACK - SIZE 3	I-GEL O2 RESUS PACK, SMALL ADULT, SIZE 3
I-GEL	I-GEL	I-GEL	I-GEL	I-GEL
8704000	8704030	8705000	8705030	8800000
I-GEL O2 RESUS PACK - SIZE 4	I-GEL O2 RESUS PACK, SMALL ADULT, SIZE 3	I-GEL O2 RESUS PACK - SIZE 5	I-GEL O2 RESUS PACK, LARGE ADULT, SIZE 5	AIRWAY SUPPORT STRAP
I-GEL	I-GEL	I-GEL	I-GEL	I-GEL