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)

Suction Systems
These are class IIA medical devices, in accordance with rule 5 of Annex IX of the Medical Devices Directive 93/42/EEC (classification.doc)
These devices are supplied sterile and are made for Intersurgical by Vitaltec.
Essential requirements checklist is on IQR139.
Incoming product specification (IQR98), design drawings are on IQR69.
Device Master Records are held in Intersurgical DSF folders.
Device History Records are held at Vitaltec.
Labelling information and IFU are on the primary packaging of each device.
Box labelling information is provided to by Intersurgical to Vitaltec with each purchase order for product.
Product realisation processes are referenced in IQM section 7.1

Product Codes
As listed in EFACS MPF Details under group DCSUCSYS.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.

Digitally signed by Durdun Margareta
Date: 2024.12.23 12:42:06 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

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