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

December, 2020

EC Declaration of Conformity Group: DCRESUS.DOC **DOC 37**

Products:

7150000	7150006	7151000	7151001	7151006
BVM RESUS INFANT 280ML BAG, PRV 40cmH20, SIZE 1 MASK	BVM RESUSCITATOR, 280ML BAG, DETACHABLE O2 RESERVOIR BAG	BVM RESUSCITATOR PAED 550ML BAG PRV 40cm H20, SIZE 3 MASK	BVM RESUSCITATOR PAED 550ML BAG PRV 40CM H2O SIZE 3 MASK	BVM RESUSCITATOR PAED 550ML PRV 40CM H20 ADJ PEEP SIZE 3 MSK
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
7152000	7152003	7152005	7152006	7152012
BVM RESUSCITATOR, ADULT, 1.5LTR BAG, SIZE 5 MASK	BVM MAN RESUS B/SYS SM ADULT/PAED 1L BAG SIZE 3 & 5 MASK	BVM RESUSCITATOR ADULT 1.5L BAG ADJ. PEEP VALVE SIZE 5 MASK	BVM RESUSCITATOR ADULT 1.5L BAG ADJ. PEEP VALVE SIZE 5 MASK	BVM RESUSCITATION ADULT 1.5L BAG, SIZE 3 & 5 MASK
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
7152060	7153000	7153006	7154000	7155000
BVM RESUSCITATOR ADULT 1.5L BAG PRV 60cmH2O SIZE 5 MASK	BVM RESUS SMALL ADULT/PAED 1LTR BAG PRV 40cmH20 SIZE 4 MASK	BVM RESUSCITATOR SM ADULT/PAED 1L BAG PRV 40CM H20 ADJ PEEP	BVM RESUSCITATOR, PAEDIATRIC, 550ML BAG PRV 40cmH20 SZ 1 MSK	BVM RESUSCITATOR INFANT 280ML BAG PRV 40CM H20 SIZE 1 MASK
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS
7156000	7161000	7161001		
BVM RESUSCITATOR PAED 550ML BAG PRV 40cm H20 SIZE 1 MASK	PEEP VALVE ADAPTOR	PEEP VALVE ADAPTOR		
ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS	ANAESTHETIC SYSTEMS		

INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
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.

Authorised Representative in the European Economic Area (EEA):
UAB Intersurgical (address: Arnioniu g. 60, Pabradė, LT-18170, Lithuania)

Resuscitation Systems
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 – 36086, 46823, 46634
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 DCRESUS.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

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