

## 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)

### Catheter Mounts

**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 – 42476, 46819

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 DCCATHMT.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 19  
Valid from 1 January 2021  
DCCATHMT.DOC

**Appendix for Declaration of Conformity Group: DCCATHMT.DOC**

<b>Product Code</b>	<b>Product Description</b>
3501000	FLEXIBLE FIXED ELBOW CATHETER MOUNT 22F-22M/15F >= 170MM
3501000S	FLEXIBLE FIXED ELBOW CATHETER MOUNT, 22F - 22M/15F, ≥170MM - STERILE
3502000	SUPERSET FIXED ELBOW CATHETER MOUNT 22F-22M/15F >= 70MM-150MM
3502000S	SUPERSET FIXED ELBOW CATHETER MOUNT, 22F - 22M/15F-STERILE
3504000	SUPERSET STRAIGHT CATHETER MOUNT 22F-22M/15F >= 70MM-150MM
3504000S	SUPERSET STRAIGHT CATHETER MOUNT, 22F - 22M/15F, ≥70MM-150MM - STERILE
3504006	SUPERSET STRAIGHT CATHETER MOUNT, 15M - 15F, ≥70MM-150MM
3505000	FLEXIBLE DOUBLE SWIVEL CATHETER MOUNT 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F >= 170MM
3505000S	FLEXIBLE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥170MM - STERILE
3506000	FLEXIBLE DOUBLE SWIVEL CATHETER MOUNT 22F-22M/15F >= 170MM
3507002	FLEXIBLE DOUBLE SWIVEL CATHETER MOUNT, 15M - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥340MM
3508000	FLEXIBLE FIXED ELBOW CATHETER MOUNT 22F - FLIP TOP CAP WITH 7.6MM PORT - 22M/15F>=170MM
3511000	FLEXIBLE STRAIGHT CATHETER MOUNT 22F-22M/15F >=170MM
3511012	FIXED ELBOW CATHETER MOUNT, 22F - 22M/15F, ≥170MM
3512000	SUPERSET DOUBLE SWIVEL CATHETER MOUNT 22F-22M/15F >= 70MM-150MM
3514000	SUPERSET FIXED ELBOW CATHETER MOUNT, 22F - LUER PORT - 22M/15F >= 70MM-150MM
3515000	FLEXIBLE FIXED ELBOW CATHETER MOUNT 22F - LUER PORT - 22M/15F >= 170MM
3516000	FLEXIBLE DOUBLE SWIVEL CATHETER MOUNT, 22F - FLIP TOP CAP WITH 7.6MM PORT - 22M/15F >= 170MM
3516000S	FLEXIBLE DOUBLE SWIVEL CATHETER MOUNT, 22F - FLIP TOP CAP WITH 7.6MM PORT - 22M/15F, ≥170MM - STERILE
3517000	FLEXIBLE STRAIGHT CATHETER MOUNT 22F - 15M, WITH ELASTOMETRIC CONNECTOR >= 170MM
3520000	SUPERSET DOUBLE SWIVEL CATHETER MOUNT, 22F - FLIP TOP CAP WITH 7.6MM PORT - ≥ 70MM-150MM
3520000S	SUPERSET DOUBLE SWIVEL CATHETER MOUNT, 22F - FLIP TOP CAP WITH 7.6MM PORT - 22M/15F, ≥70MM-150MM - STERILE
3521000	SUPERSET DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥70MM-150MM
3521000S	SUPERSET DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥70MM-150MM - STERILE
3521001	SUPERSET DOUBLE SWIVEL CATHETER MOUNT, 15M - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥70MM-150MM
3521002	SUPERSET DOUBLE SWIVEL CATHETER MOUNT 22F - 22M/15FWITH LUER ELBOW ≥70MM-150MM
3532000	FLEXIBLE FIXED ELBOW PAEDIATRIC/NEONATAL CATHETER MOUNT, 15M-7.6MM PORT-15F, ≥100MM
3533000	FLEXIBLE FIXED ELBOW PAEDIATRIC/NEONATAL CATHETER MOUNT, 15M - 15F, ≥50MM
3534000	SUPERSET FIXED ELBOW PAEDIATRIC/NEONATAL CATHETER MOUNT, 15M - 7.6MM PORT - 8.5F, ≥ 49MM-100MM
3535000	SUPERSET FIXED ELBOW CATHETER MOUNT, 15M - 7.6MM PORT - 15F, ≥49MM-100MM
3535003	SUPERSET FIXED ELBOW CATHETER MOUNT, 15M - 7.6MM PORT - 22M/15F, ≥120MM
5120000	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥120MM

5120000S	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥120MM - STERILE
5120002S	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥50MM - STERILE
5120003S	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥100MM - STERILE
5120004S	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥150MM - STERILE
5120006	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - 22M/15F, ≥150MM
5120007	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT 22F-22M/15F, ≥ 400MM
5180000	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥180MM
5180000S	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥180MM - STERILE
5180001	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, WITH RED CAP, ≥180MM
5180104	SMOOTHBORE STRAIGHT CATHETER MOUNT, 22F - 15F, ≥180MM
5180104S	SMOOTHBORE STRAIGHT CATHETER MOUNT, 22F - 15F, ≥180MM - STERILE
5180114S	SMOOTHBORE FIXED ELBOW CATHETER MOUNT, 22F - LUER PORT - 22M/15F, ≥180MM - STERILE
5180193	SMOOTHBORE FIXED ELBOW CATHETER MOUNT, 22F - FLIP TOP CAP WITH 7.6MM PORT - 2M/15F, ≥ 180MM
5180197S	SMOOTHBORE FIXED ELBOW CATHETER MOUNT, 22F - 22M/15F, ≥180MM - STERILE
5180199	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - 22M/15F, ≥180MM
5180199S	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - 22M/15F, ≥180MM - STERILE
5181000	SMOOTHBORE STRAIGHT CATHETER MOUNT, 22F - 15F, ≥120MM
5181001	SMOOTHBORE STRAIGHT CATHETER MOUNT, 22F - 15F, ≥700MM
5250000	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥250MM
5250000S	SMOOTHBORE DOUBLE SWIVEL CATHETER MOUNT, 22F - DOUBLE FLIP TOP CAP WITH SEAL - 22M/15F, ≥250MM - STERILE
9120000	SMOOTHBORE STRAIGHT CATHETER MOUNT 22F - 22M/15F, ≥ 210MM