

## 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)

### Bougies and Stylets

**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 Well Lead Medical Co Ltd.

Essential requirements checklist is on IQR139.

Incoming product specification (IQR98), design drawings are on IQR69.

Externally manufactured materials specifications and Device Master Records held by Well Lead.

Instruction sheet code 5355 or 5359 is provided with each box of products.

Labelling information is on the primary packaging, for each device.

Box labelling information is provided by Intersurgical to Well Lead 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 DCBOUG.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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