

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 516824****Issued To:**

**Smiths Medical International Ltd  
St Crispin Way  
Haslingden, Rossendale  
Lancashire  
BB4 4PW  
United Kingdom**

In respect of:

**See certificate scope page.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Gary Fenton, Global Assurance Director

First Issued: **23 March 2007**

Date: **29 September 2014**

Expiry Date: **22 March 2017**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 516824

## Certificate Scope:

**The design and manufacture of the following sterile and end-user sterilisable medical devices:**

**Patient pressure monitoring systems**

**Infusion systems**

**Peripheral intravenous catheters and obturators**

**Drapes**

**Interventional imaging systems**

**Surgical procedure packs:**

**Pressure monitoring procedure packs**

**Vascular access procedure packs**

**Interventional imaging procedure packs**

**Operating room procedure packs**

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 516824**  
 Date: **29 September 2014**  
 Issued To: **Smiths Medical International Ltd**  
**St Crispin Way**  
**Haslingden, Rossendale**  
**Lancashire**  
**BB4 4PW**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Bioster S.p.A. Via Einaudi 9, 1-24050 Calcinato (BG) Italy	ETO Sterilization
Smiths Medical ASD Inc. 6250 Shier Rings Road Dublin Ohio 43016 USA	Control of Sterilization Manufacture
Smiths Medical ASD, Inc. 1265 Grey Fox Road St Paul MN 55112 USA	Design

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**United Kingdom**

Subcontractor:	Service(s) supplied
Smiths Medical ASD, Inc. 201 West Queen Street Southington CT 06489 USA	Design
Smiths Medical International Ltd 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	Manufacture
Smiths Medical International Ltd Boundary Road Hythe CT21 6JL United Kingdom	Design

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Subcontractor:	Service(s) supplied
Smiths Medical Italia S.r.L Via della Stazione 2 Latina Scalo Latina 04013 Italy	Manufacture
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue du Parc, 29 B-4800 Verviers Belgium	ETO Sterilization
Sterigenics UK Limited Cotes Park Estate Somercoates Alfreton Derbyshire DE55 4NJ United Kingdom	ETO Sterilization

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### Subcontractor:

### Service(s) supplied

Steril Verona S.r.l.  
 Via S. Giuseppe, 31  
 37060 Erbè  
 Verona  
 Italy

**ETO Sterilization**

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# EC Certificate - Full Quality Assurance System

## Certificate History

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Date	Reference Number	Action
23 March 2007		First Issue based on CE 01478
19 March 2012	7802964	Addition of 'end-user sterilisable' devices to the scope; Administrative changes to scope wording; Administrative address changes to significant subcontractors Smiths Medical Italia S.r.l and Smiths Medical International Ltd; Certificate Renewal
27 August 2012	7844738	Removal of 'ICU procedure packs', 'Pain management kits' and 'Airway management kits' from the scope; Addition of 'Design' activity to Smiths Medical, Glasgow; Addition of Smiths Medical, Grasbrunn, Smiths Medical, St Paul, and Smiths Medical, Southington as significant subcontractors for Design activities
29 August 2013	8031887	Addition of Sterigenics Belgium (Petit-Rechain) SA, Belgium as significant subcontractor for ETO sterilization activity

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Date	Reference Number	Action
26 February 2014	8109531	Removal of `Design` service for the subcontractor Smiths Medical, Cumbernauld Removal of Smiths Medical Deutschland as a significant subcontractor Addition of Smiths Medical, Hythe as a significant subcontractor for `Design`
29 September 2014	8215960	Addition of Smiths Medical ASD, Dublin to the list of significant sub-contractors.

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