

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 685113****Issued To:**

Smiths Medical ASD, Inc
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

In respect of:

Those aspects of annex V relating to the securing and maintaining of sterility of class I sterile:

- **Regional anaesthesia locks, specimen trap, securement and laryngotracheal kit**
- **Vascular access connectors and clamps**
- **Infusion disposables gravity administration sets**
- **Intubation systems accessories**
- **Convective warmers blankets**

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-06-21**

Date: **2019-06-21**

Expiry Date: **2024-05-26**

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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.

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Supplementary Information to CE 685113

Issued To:

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NBOG code(s)	Device Name	Intended purpose
Class Is		
NBOG code(s)	Device subcategory	NA for class Is devices
MD0102 MD0101	Sterile regional anaesthesia locks, specimen trap, securement and laryngotracheal kit	NA
MD0101	Sterile vascular access connectors and clamps	NA
MD0101	Sterile infusion disposables gravity administration sets	NA
MD0101	Sterile intubation systems accessories	NA
MD1403	Sterile convective warmers blankets	NA

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

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55442
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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No.4, Parque, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425, Mexico	Manufacture
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	Manufacture

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Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 10 Bowman Drive Keene NH 03431 USA	Manufacture
Smiths Medical ASD Inc. 201 West Queen Street Southington CT 06489 USA	Manufacture
Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	EU Representative Manufacture

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Subcontractor:	Service(s) supplied
Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth Germany	Manufacture
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF UK	Manufacture
Smiths Medical International Ltd 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	Manufacture

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Subcontractor:	Service(s) supplied
Smiths Medical Italia S.r.l Via della Stazione 2 Latina Scalo Latina 04100 Italy	Packaging
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	ETO Sterilization
Sterilization Services of Tennessee 2396 Florida Street Memphis Tennessee 38109 USA	ETO Sterilization

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Certificate History

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Date: **2019-06-21**
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Date	Reference Number	Action
Current	9714832	First Issue.

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