

EC Certificate - Full Quality Assurance System

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

No. CE 669121
Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

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):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-07-20**

Date: **2018-05-09**

Expiry Date: **2023-03-18**

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Page 1 of 2

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 669121

Certificate Scope:

The design, development and manufacture of:

Sterile Disposable infusion kits including cassette, tubes, connectors, needles

Patient warming units

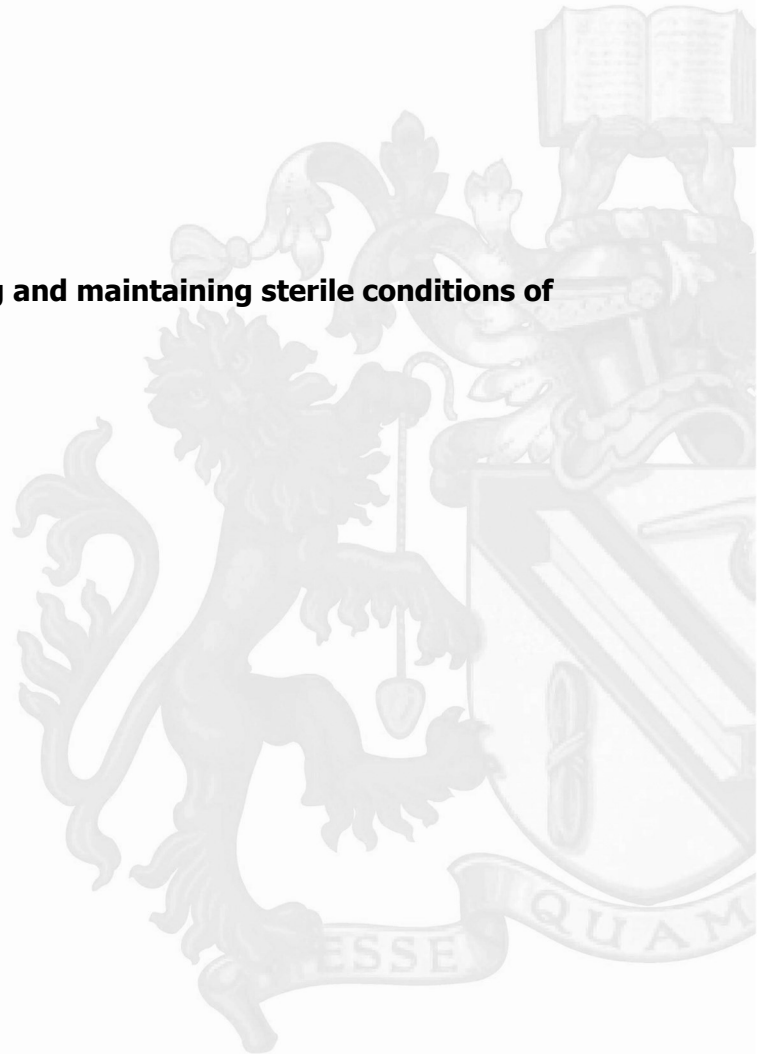
Blood and Fluid Warmers units

Sterile Blood and Fluid Warmers disposables sets

Sterile Central Implantable Access Systems

Sterile Peripheral Implantable Access Systems

Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets.

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List of Significant Subcontractors

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

Certificate No: **CE 669121**
 Date: **2018-05-09**
 Issued To: **Smiths Medical ASD Inc.
 6000 Nathan Lane North
 Minneapolis
 Minnesota
 55442
 USA**

Subcontractor:	Service(s) supplied
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 USA	Manufacture
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	ETO Sterilization
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	ETO Sterilization
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	Gamma Sterilization
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	Design Manufacture

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Subcontractor:	Service(s) supplied
Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	Manufacture
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	Regulatory Compliance
Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	Manufacture

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Subcontractor:	Service(s) supplied
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF United Kingdom	EU Representative
Sterigenics US, LLC 10811 Withers Cover Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	Gamma Sterilization

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Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	ETO Sterilization
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	ETO Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**
Date: **2018-05-09**
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Date	Reference Number	Action
20 July 2017	8691798	First issue, transferred from another notified body.
Current	8893340	Renewal, scope rewording, scope reduction, subcontractor removal, correction of subcontractor address and activities

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