

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

## EN ISO 13485:2016

The management system is applicable to:

Design, manufacture, inspection, storage and distribution of  
Pressure Monitoring, Infusion Disposables, Interventional  
Imaging, Neurosurgery, Vascular Access.

The Servicing of active medical devices.

**Certificate Number:**

119-04 C

**Initial Certification Date:**

08 June 2004

**Date of Certification Decision:**

25 June 2018

**Issuing Date:**

25 June 2018

**Valid Until:**

24 June 2021



061

**Calin Moldovean**

President, Business Assurance

AMTAC Certification Services Limited, T/A Intertek;  
Milton Keynes, UK

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Certification Services Ltd a wholly owned subsidiary  
of Intertek Holdings Ltd"

Intertek Certification Limited is a  
UKAS accredited body under  
schedule of Accreditation No. 061





## CERTIFICAT DE ÎNREGISTRARE

Se certifică prin prezenta că sistemul de management al:

# SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn,  
Germania

Pentru locații și domenii suplimentare, vedeți anexa

a fost înregistrată de către Intertek deoarece se  
conformează cerințelor:

## EN ISO 13485:2016

### Sistemul de management este aplicabil pentru:

Proiectarea, fabricarea, inspectarea,  
depozitarea și distribuirea Dispozitivelor de  
Monitorizare a Tensiunii, a Dispozitivelor de  
Injectare de Unică Folosință, a Dispozitivelor  
pentru Intervenții, Imagistică, Neurochirurgie,  
Acces Vascular.

Service-ul dispozitivelor medicale active.

Certificat Număr:

119-04 C

Data Certificării Inițiale:

08 Iunie 2004

Data Deciziei Certificării:

25 Iunie 2018

Data Emiterii:

25 Iunie 2018

Valabil Până la:

24 Iunie 2021



Semnătura - indescifrabilă

**Calin Moldovean**

Președinte, Business Assurance

AMTAC Certification Services Limited, T/A Intertek;  
Milton Keynes, UK

“Prezentul Certificat este proprietatea AMTAC  
Certification Services Ltd sucursală deținută integral de  
către Intertek Holdings Ltd”

Intertek Certification Limited este organism acreditat UKAS  
conform graficului de Acreditare nr. 061

\*\*\*\*\*

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justiției, certific exactitatea acestei traduceri cu textul  
înscrisului original în limba engleza, ce a fost vizat de mine.



Traducător autorizat  
Nr. 2769/2015



În emiterea prezentului certificat, Intertek nu-și asumă nicio responsabilitate față de nicio parte, alta decât Clientul, și aceasta numai în conformitate cu Acordul de Certificare. Validitatea prezentului certificat se supune păstrării de către organizație a sistemului de management în conformitate cu cerințele Intertek cu privire la certificarea sistemelor. Validitatea acestuia poate fi confirmată prin email la [certificate.validation@intertek.com](mailto:validation@intertek.com) sau prin scanarea codului din dreapta cu un smartphone. Certificatul rămâne proprietatea Intertek, căreia îi trebuie returnat la cerere.

# EC Certificate - Full Quality Assurance System

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

**No.****CE 661325****Issued To:**

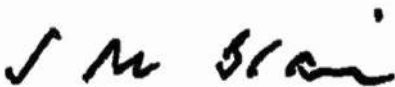
**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2017-06-28**

Date: **2017-06-28**

Expiry Date: **2022-06-27**

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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 661325

## Certificate Scope:

### **The design, development and manufacture of sterile:**

**Breathing Systems, Drainage Devices, Feeding Devices, Filtration Devices for Breathing Circuits, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology Sampling Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Accessories, Resuscitation Devices, Suction Catheters, Tracheostomy Tubes, Vascular Access Devices**

### **The design, development and manufacture of non-sterile:**

**Breathing Systems, Intubation Systems, Resuscitation Devices, Gynecologic Pessaries, Tracheostomy Tubes, Oxygen and Humidity Management Devices**



First Issued: **2017-06-28**

Date: **2017-06-28**

Expiry Date: **2022-06-27**

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Page 2 of 2

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

Certificate No: **CE 661325**  
 Date: **2017-06-28**  
 Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Brightwake Limited Lowmoor Business Park Kirkby-in-Ashfield Nottinghamshire NG17 7JZ United Kingdom	Manufacture
GaleMed Corporation No. 87, Li-Gong 2nd Road Wu-Jia YILAN 268 Taiwan	Manufacture
GE Medical Pollards Wood Nightingales Lane Chalfont Saint Giles HP8 4SP United Kingdom	Manufacture

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**CT21 6JL**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Koo Medical Equipment (Shanghai) Co., Ltd 100 Zhongde Road Dakun Industrial Park Songjiang, Shanghai 201614 China	Manufacture
Pentair Filtration Solutions 1350 Hammond Road St. Paul Minnesota 55110 USA	Crucial Supplier
Quadrant EPP Belgium N.V. Industriepark Noord Robert Tavernierlaan 2 Tielt 8700 Belgium	Manufacture

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**Kent**  
**CT21 6JL**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4 Parque, Industrial Internacional Tijuana 22425 Mexico	<b>Manufacture</b>
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	<b>Manufacture</b>

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**CT21 6JL**  
**United Kingdom**

**Subcontractor:****Service(s) supplied**

Smiths Medical ASD Inc.  
10 Bowman Dr.  
Keene  
New Hampshire  
03431  
USA

**Manufacture**

Smiths Medical ASD Inc.  
1265 Grey Fox Road  
St Paul  
Minnesota  
55112  
USA

**Manufacture**

Smiths Medical ASD Inc.  
201 West Queen St.,  
Southington  
Connecticut  
06489  
USA

**Manufacture**

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**Kent**  
**CT21 6JL**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 6250 Shier Rings Road Dublin Ohio 43016 USA	Manufacture
Smiths Medical ASD Inc. 9124 Polk Lane, Suite 101 Olive Branch Mississippi 38654 USA	Distribution
Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	Manufacture

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**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Smiths Medical Gary 5700 W 23rd Ave Gary Indiana 46406 USA	Manufacture
Smiths Medical International Ltd 52 Grayhill Rd Cumbernauld Glasgow G68 9HQ United Kingdom	Manufacture
Smiths Medical International Nijmegen Bijsterhuizen 22-08 6604 LD Wijchen The Netherlands	Distribution

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**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Smiths Medical Italia Srl Via della Stazione, 2 Latina Scalo 04100 Italy	Packaging
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 B-4800 Verviers Belgium	ETO Sterilization
Sterigenics UK Limited Cotes Park Estate Somercoates Alfreton DE55 4NJ United Kingdom	ETO Sterilization

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**United Kingdom**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
Sterigenics, LLC 1700 College Blvd. West Memphis Arkansas 72301 USA	Gamma Sterilization
Sterilization Services of Tennessee, Inc 2396 Florida Street Memphis Tennessee 38109 USA	ETO Sterilization

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**United Kingdom**

Subcontractor:	Service(s) supplied
STERIS ISOMEDIX Services, Inc 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
UPG Avenida La Cuspide #1 Parque Industrial Tecnomex Del. Playas de Tijuana Tijuana Baja California 22700 Mexico	Manufacture
Velcro USA Inc. 95 Sundial Avenue Manchester New Hampshire 03103-7206 USA	Crucial Supplier

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# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 661325**  
Date: **2017-06-28**  
Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

Date	Reference Number	Action
Current	8603100 8603169	First issue. Transferred from another Notified Body. Certificate renewal.

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