intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

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

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.

UKAS MANAGEMENT SYSTEMS
061

Calin Moldovean
President, Business Assurance

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

"This certificate is the property of AMTAC 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

Traducere din limba engleză

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

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

061

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.

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 Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015

MINISTERUL JUSTIȚIEI MUȘUROIA MIRELA Aut. Nr. 2769 Engleză/Franceză TRADUCĂTOR AUTORIZAT

S.C. CRAZY PRICE MEDICAL IMPORT EXPORT S.R.L. Conform cu originalul

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 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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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**

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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Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **Hythe** **Kent** **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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Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **Hythe** **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	**Manufacture**
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	**Manufacture**

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Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **Hythe** **Kent** **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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EC Certificate - Full Quality Assurance System

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

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Date:	**2017-06-28**
Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **Hythe** **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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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Date:	**2017-06-28**
Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **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 Grayshill 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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EC Certificate - Full Quality Assurance System

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

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Date:	**2017-06-28**
Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **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 Somercotes Alfreton DE55 4NJ United Kingdom	**ETO Sterilization**

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Date:	**2017-06-28**
Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **Hythe** **Kent** **CT21 6JL** **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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Date:	**2017-06-28**
Issued To:	**Smiths Medical International Ltd.** **Boundary Road** **Hythe** **Kent** **CT21 6JL** **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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