

# 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

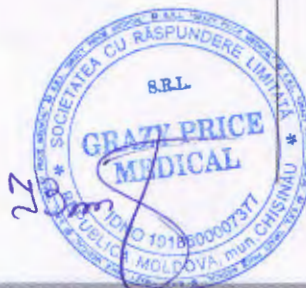
**Calin Moldovean**

President, Business Assurance

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

"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



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO13485\_2012-UKAS-EN-A4-12.dec.17





## 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 Justitiei, certific exactitatea acestei traducerii 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 [certificates.validation@intertek.com](mailto:certificates.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):

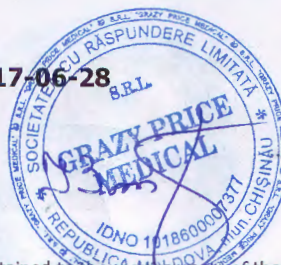


Stewart Brain, Head of Compliance & Risk -  
Medical Devices

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

Date: **2017-06-28**

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



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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 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**

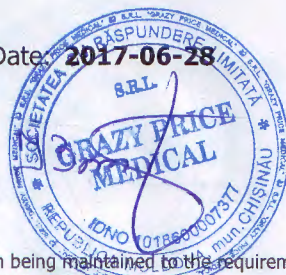
**The design, development and manufacture of non-sterile:**

**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

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.

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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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# EC Certificate - Full Quality Assurance System

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

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**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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# EC Certificate - Full Quality Assurance System

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

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

### Subcontractor:

### Service(s) supplied

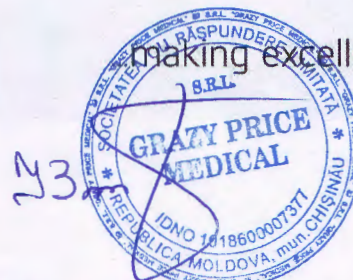
Smiths Healthcare Manufacturing  
 SA de CV  
 Avenida Calidad No.4  
 Parque, Industrial Internacional  
 Tijuana  
 22425  
 Mexico

**Manufacture**

Smiths Healthcare Manufacturing  
 SA de CV  
 Carretera Miguel Alemán Km 21.7  
 Parque Industrial Monterrey  
 Apodaca  
 Nuevo León  
 66603  
 Mexico

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**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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**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

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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

Smiths Medical Gary  
 5700 W 23rd Ave  
 Gary  
 Indiana  
 46406  
 USA

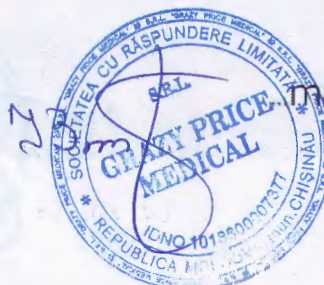
**Manufacture**

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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# 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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 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

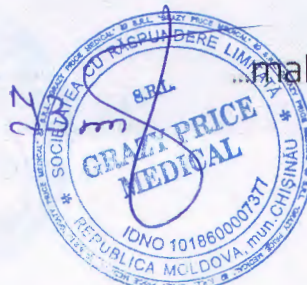
Packaging

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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# 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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**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

### Subcontractor:

### Service(s) supplied

Sterigenics US, LLC  
 344 Bonnie Circle  
 Corona  
 California  
 92880  
 USA

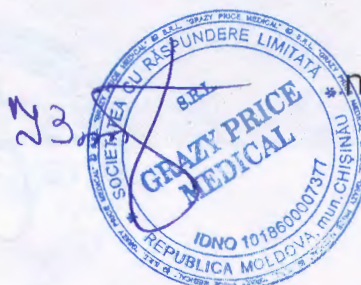
**Gamma Sterilization**

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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# 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

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<br>8603169 | First issue. Transferred from another Notified Body.<br>Certificate renewal. |



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Page 1 of 1

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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.



# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Nr.

**CE 661325**

Titular:

**Smiths Medical International Ltd.**

**Boundary Road**

**Hythe**

**Kent**

**CT21 6JL**

**Marea Britanie**

Obiect:

**Consultati pagina cu obiectul certificatului.**

pe baza examinarii noastre a sistemului de asigurare a calitatii conform cerintelor Directivei Consiliului 93/42/CEE, Anexa II excluzand Sectiunea 4. Sistemul de asigurare a calitatii indeplineste cerintele Directivei. Pentru lansarea pe piata a produselor din clasa III este necesar certificatul mentionat in Anexa II, Sectiunea 4.

Pentru si in numele BSI, organ de certificare in acceptiunea sus-mentionatei Directive (Organ de certificare cu numarul 0086):



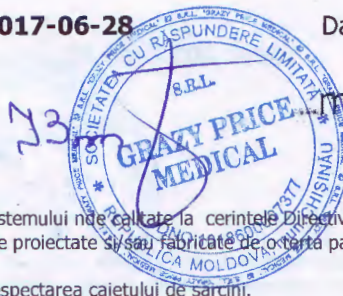
Stewart Brain, Sef compartiment conformitate si risc

Dispozitive medicale

Prima editie: **2017-06-28**

Data: **2017-06-28**

Data expirarii: **2022-06-27**



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Pagina 1 din 2

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului de calitate la cerintele Directivei dovedita de organul de certificare care supravegheaza compania. Prezenta aprobare exclude toate produsele proiectate si/sau fabricate de o terta parte on in numele companiei care detine prezentul certificat, cu exceptia unui acord contrar, incheiat cu BSI. Prezentul certificat a fost redactat electronic si este conditionat de respectarea caietului de sarcini.

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.





Certificat nr.: CE 661325

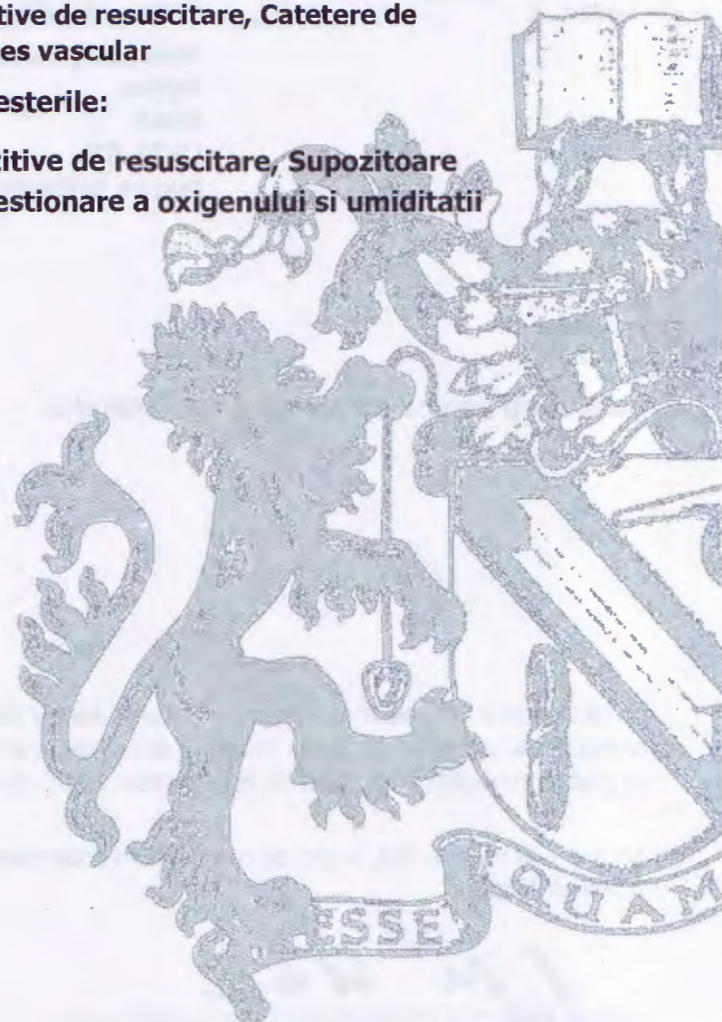
## Obiectul certificatului:

### Proiectarea, dezvoltarea si fabricatia produselor sterile:

**Sisteme de respiratie, Dispozitive de drenaj, Dispozitive de nutritie, Dispozitive de filtrare pentru Circuite respiratorii, Consumabile pentru perfuzii, Sisteme de intubatie, Dispozitive de prelevare a probelor pentru obstetrica si ginecologie, Dispozitive de gestionare a oxigenului si umiditatii, Accesorii de control al presiunii, Dispozitive de resuscitare, Catetere de absorbtie, Tuburi de traheostomie, Dispozitive de acces vascular**

### Proiectarea, dezvoltarea si fabricatia de produse nesterile:

**Sisteme de respiratie, Sisteme de intubatie, Dispozitive de resuscitare, Supozitoare vaginale, Tuburi de traheostomie, Dispozitive de gestionare a oxigenului si umiditatii**

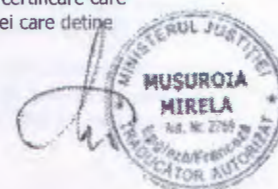
Prima editie: **2017-06-28**Data: **2017-06-28**Data expirarii: **2022-06-27**

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Pagina 2 of 2

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului de calitate la cerintele Directivei dovedita de organul de certificare care supravegheaza compania. Prezenta aprobare exclude toate produsele proiectate si/sau fabricate de o alta parte on in numele companiei care detine prezentul certificat, cu exceptia unui acord contrar, incheiat cu BSI.  
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# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatile aferente produsului, certificat prin:

Certificat nr.: **CE 661325**  
 Data: **2017-06-28**  
 Titular: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

### Servicii prestate

Brightwake Limited  
 Lowmoor Business Park  
 Kirkby-in-Ashfield  
 Nottinghamshire  
 NG17 7JZ  
 Marea Britanie

Fabricatie

GaleMed Corporation  
 Nr. 87, Li-Gong 2nd Road  
 Wu-Jia  
 YILAN 268  
 Taiwan

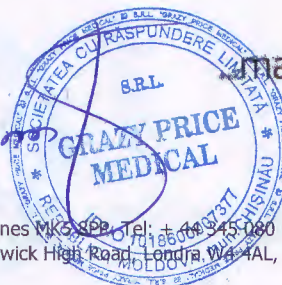
Fabricatie

GE Medical  
 Pollards Wood  
 Nightingales Lane  
 Chalfont Saint Giles  
 HP8 4SP  
 Marea Britanie

Fabricatie

Pagina 1 din 9

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: +44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.



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# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

### Servicii prestate

Koo Medical Equipment (Shanghai)  
 Co., Ltd  
 100 Zhongde Road  
 Dakun Industrial Park  
 Songjiang, Shanghai 201614  
 China

Fabricatie

Pentair Filtration Solutions  
 1350 Hammond Road  
 St. Paul  
 Minnesota  
 55110  
 USA

Furnizor crucial

Quadrant EPP Belgium N.V.  
 Industriepark Noord  
 Robert Tavernierlaan 2  
 Tiel  
 8700  
 Belgia

Fabricatie

Pagina 2 din 9

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PI. Tel: + 44 (0)1908 9000 BSI  
 Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A  
 membra a grupului BSI.



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**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

### Servicii prestate

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

Fabricatie

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

Fabricatie

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

Fabricatie

Pagina 4 din 9

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.



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# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**  
Data: **2017-06-28**  
Titular: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

Smiths Medical ASD Inc.  
6250 Shier Rings Road  
Dublin  
Ohio  
43016  
USA

### Servicii prestate

Fabricatie

Smiths Medical ASD Inc.  
9124 Polk Lane, Suite 101  
Olive Branch  
Mississippi  
38654  
USA

### Distributie

Smiths Medical Republica Ceha a.s.  
Olomoucká 306  
753 01 Hranice  
Republica Ceha

### Fabricatie

Pagina 5 din 9

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: +44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.



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# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: **CE 661325**  
Data: **2017-06-28**  
Titular: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

### Servicii prestate

Smiths Medical Gary  
5700 W 23rd Ave  
Gary  
Indiana  
46406  
USA

Fabricatie

Smiths Medical International Ltd  
52 Grayhill Rd  
Cumbernauld  
Glasgow  
G68 9HQ  
Marea Britanie

Fabricatie

Smiths Medical International  
Nijmegen  
Bijsterhuizen 22-08  
6604 LD Wijchen  
Olanda

Distributie

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Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.





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Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

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**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

Smiths Medical ASD Inc.  
6250 Shier Rings Road  
Dublin  
Ohio  
43016  
USA

### Servicii prestate

Fabricatie

Smiths Medical ASD Inc.  
9124 Polk Lane, Suite 101  
Olive Branch  
Mississippi  
38654  
USA

### Distributie

Smiths Medical Republica Ceha a.s.  
Olomoucká 306  
753 01 Hranice  
Republica Ceha

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Pagina 5 din 9

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# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**  
Data: **2017-06-28**  
Titular: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

Smiths Medical Italia Srl  
Via della Stazione, 2  
Latina Scalo  
04100  
Italia

### Servicii prestate

Ambalare

Sterigenics Belgium  
(Petit-Rechain) SA  
Zoning Industriel de Petit-Rechain  
Avenue Andre Ernst 21  
B-4800 Verviers  
Belgium

### Sterilizare ETO

Sterigenics UK Limited  
Cotes Park Estate  
Somercotes  
Alfreton  
DE55 4NJ  
Marea Britanie

### Sterilizare ETO

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# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

Sterigenics US, LLC  
344 Bonnie Circle  
Corona  
California  
92880  
USA

### Servicii prestate

**Sterilizare cu raze gamma**

Sterigenics, LLC  
1700 College Blvd.  
West Memphis  
Arkansas  
72301  
USA

**Sterilizare cu raze gamma**

Sterilization Services of  
Tennessee, Inc  
2396 Florida Street  
Memphis  
Tennessee 38109  
USA

**Sterilizare ETO**

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# Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**  
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 Titular: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

STERIS ISOMEDIX Services, Inc  
 7685 Saint Andrews Avenue  
 San Diego  
 California 92154  
 USA

### Servicii prestate

**Sterilizare ETO**

UPG  
 Avenida La Cuspide #1  
 Parque Industrial Tecnomex  
 Del. Playas de Tijuana  
 Tijuana  
 Baja California  
 22700  
 Mexic

### Fabricatie

Velcro USA Inc.  
 95 Sundial Avenue  
 Manchester  
 New Hampshire  
 03103-7206  
 USA

### Furnizor crucial

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# Certificat CE - Sistem Integral de Asigurare a Calitatii – Istoricul certificatului

Certificat nr.: **CE 661325**  
 Data: **2017-06-28**  
 Titular: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

| Data    | Numar de referinta | Actiune                                                                             |
|---------|--------------------|-------------------------------------------------------------------------------------|
| Curenta | 8603100<br>8603169 | Prima editie. Transferat de alt organ de certificare.<br>Reinnoirea certificatului. |

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 Prezentul certificat a fost redactat electronic si este conditionat de respectarea culetelui de sarcini

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 Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A  
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Subsemnata MUSUROIA MIRELA, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul inscrisului original in limba engleza, ce a fost vizat de mine.

Traducator autorizat

Nr. 2769/2015