

# EC Certification



## EC DESIGN EXAMINATION CERTIFICATE Directive 93/42/EEC for Medical Devices, Annex II (4)

We hereby declare that a design examination has been carried out on the device(s) listed hereafter following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed hereafter conforms with the relevant provisions of Annex II Section 4 of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products\*.

## SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

Central venous catheters:

- standard sets
- standard kits
- custom sets

\*For CE marking the class III devices covered by this certificate, an EC certificate according to Annex II (3) is also required.

Certificate Number: 119-05 B DE  
Initial Certification Date: 01 September 2006  
Certificate Effective Date: 07 March 2017  
Certificate Expiry Date: 06 March 2022

Barry A. Fitch  
AMTAC Certification Services Limited, Milton Keynes, UK  
This certificate is the property of AMTAC Certification Services Ltd



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 organization 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.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

# Certificat CE

## Intertek

**CERTIFICAT DE EXAMINARE CE DE TIP**  
**Directiva 93/42/CEE pentru Dispozitive Medicale, Anexa II (4)**

Declarăm prin prezenta că a fost efectuată o examinare a tipului dispozitivului(elor) specificate în continuare în prezenta, conform cerințelor legislației naționale britanice la care este supusă subsemnata, cu transpunerea Anexei II Secțiunea 4 la Directiva 93/42/CEE privind dispozitivele medicale. Certificăm că tipul dispozitivului(elor) menționate în continuare în prezenta este în conformitate cu prevederile relevante ale Anexei II Secțiunea 4 din legislația menționată mai sus și, prin urmare, organizația are dreptul de a utiliza marcajul CE 0473 pe produsele specificate mai jos\*.

## SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germania

Catetere venoase centrale:

- seturi standard
- truse standard
- seturi la comandă

\* Pentru a primi marcajul CE, dispozitivele din clasa III acoperite de acest certificat necesită și un certificat CE conform Anexei II (3).

Număr Certificat: Inițial 119-05 B DE  
Data certificării: 01 Septembrie 2006  
Data efectivă a certificării: 07 Martie 2017  
Data expirării certificării: 06 Martie 2022

Barry A. Fitch  
AMTAC Certification Services Limited, Milton Keynes, UK  
Acest certificat este proprietatea AMTAC Certification Services Ltd  
*Semnătură indescifrabilă*

La eliberarea acestui certificat, Intertek nu își asumă responsabilitatea față de oricare parte alta decât Clientul, și atunci doar în conformitate cu Acordul de Certificare agreeat. Valabilitatea acestui certificat este supusă menținerii, de către organizație, a sistemului în conformitate cu cerințele Intertek pentru certificarea sistemelor. Valabilitatea acestuia poate fi confirmată la [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) sau prin scanarea codului din dreapta cu un smartphone. Acest Certificat este pentru uzul exclusiv al clientului AMTAC și este eliberat în urma acordului dintre AMTAC și Clientul acesteia. Responsabilitatea și obligația AMTAC sunt în funcție de condițiile acordului. AMTAC nu își asumă responsabilitatea față de oricare parte alta decât Clientul în conformitate cu acordul, pentru nicio pierdere, cheltuială sau daună ocazională ori utilizare a acestui Certificat. Clientul este singurul autorizat pentru a permite reproducerea sau distribuția acestui Certificat. Orice utilizare a numelui AMTAC sau a uneia dintre mărcile sale pentru vânzare sau promovare a materialului testat, produs sau servicii, va fi aprobat în prealabil în scris de către AMTAC.

Acest certificat rămâne proprietatea Intertek, căreia îi va fi returnat la cerere.

Certificarea este supusă menținerii, de către organizație, a sistemului acesteia în conformitate cu regulamentele specificate în acest certificat și permite evaluări regulate și în urma cerințelor contractate ale Organismului Notificat.

AMTAC Certification Services Limited este Organism Notificat conform Directivei 93/42/CEE pentru dispozitivele medicale, cu număr de identificare 0473.



# 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





## 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:**

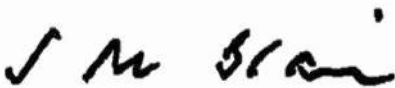
**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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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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.

This certificate was issued electronically and is bound by the conditions of the contract.

# 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)<br>Co., Ltd<br>100 Zhongde Road<br>Dakun Industrial Park<br>Songjiang, Shanghai 201614<br>China | Manufacture         |
| Pentair Filtration Solutions<br>1350 Hammond Road<br>St. Paul<br>Minnesota<br>55110<br>USA                                       | Crucial Supplier    |
| Quadrant EPP Belgium N.V.<br>Industriepark Noord<br>Robert Tavernierlaan 2<br>Tielt<br>8700<br>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<br>SA de CV<br>Avenida Calidad No.4<br>Parque, Industrial Internacional<br>Tijuana<br>22425<br>Mexico                     | <b>Manufacture</b>  |
| Smiths Healthcare Manufacturing<br>SA de CV<br>Carretera Miguel Alemán Km 21.7<br>Parque Industrial Monterrey<br>Apodaca<br>Nuevo León<br>66603<br>Mexico | <b>Manufacture</b>  |

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# EC Certificate - Full Quality Assurance System

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

| Subcontractor:                                                                               | Service(s) supplied |
|----------------------------------------------------------------------------------------------|---------------------|
| Smiths Medical ASD Inc.<br>10 Bowman Dr.<br>Keene<br>New Hampshire<br>03431<br>USA           | Manufacture         |
| Smiths Medical ASD Inc.<br>1265 Grey Fox Road<br>St Paul<br>Minnesota<br>55112<br>USA        | Manufacture         |
| Smiths Medical ASD Inc.<br>201 West Queen St.,<br>Southington<br>Connecticut<br>06489<br>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.<br>6250 Shier Rings Road<br>Dublin<br>Ohio<br>43016<br>USA                  | Manufacture         |
| Smiths Medical ASD Inc.<br>9124 Polk Lane, Suite 101<br>Olive Branch<br>Mississippi<br>38654<br>USA | Distribution        |
| Smiths Medical Czech Republic a.s.<br>Olomoucká 306<br>753 01 Hranice<br>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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 Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

| Subcontractor:                                                                                            | Service(s) supplied |
|-----------------------------------------------------------------------------------------------------------|---------------------|
| Smiths Medical Gary<br>5700 W 23rd Ave<br>Gary<br>Indiana<br>46406<br>USA                                 | Manufacture         |
| Smiths Medical International Ltd<br>52 Grayhill Rd<br>Cumbernauld<br>Glasgow<br>G68 9HQ<br>United Kingdom | Manufacture         |
| Smiths Medical International<br>Nijmegen<br>Bijsterhuizen 22-08<br>6604 LD Wijchen<br>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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Certificate No: **CE 661325**  
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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<br>Via della Stazione, 2<br>Latina Scalo<br>04100<br>Italy                                                   | Packaging           |
| Sterigenics Belgium<br>(Petit-Rechain) SA<br>Zoning Industriel de Petit-Rechain<br>Avenue Andre Ernst 21<br>B-4800 Verviers<br>Belgium | ETO Sterilization   |
| Sterigenics UK Limited<br>Cotes Park Estate<br>Somercoates<br>Alfreton<br>DE55 4NJ<br>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

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 |
|---------------------------------------------------------------------------------------------------------|---------------------|
| Sterigenics US, LLC<br>344 Bonnie Circle<br>Corona<br>California<br>92880<br>USA                        | Gamma Sterilization |
| Sterigenics, LLC<br>1700 College Blvd.<br>West Memphis<br>Arkansas<br>72301<br>USA                      | Gamma Sterilization |
| Sterilization Services of<br>Tennessee, Inc<br>2396 Florida Street<br>Memphis<br>Tennessee 38109<br>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

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 |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| STERIS ISOMEDIX Services, Inc<br>7685 Saint Andrews Avenue<br>San Diego<br>California 92154<br>USA                                    | ETO Sterilization   |
| UPG<br>Avenida La Cuspide #1<br>Parque Industrial Tecnomex<br>Del. Playas de Tijuana<br>Tijuana<br>Baja California<br>22700<br>Mexico | Manufacture         |
| Velcro USA Inc.<br>95 Sundial Avenue<br>Manchester<br>New Hampshire<br>03103-7206<br>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.

# 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 nde 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 nde 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.

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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.

# 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:

### 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**

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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:

### 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  
Tielt  
8700  
Belgia

**Fabricatie**

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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:****Servicii prestate**

Smiths Healthcare Manufacturing  
SA de CV  
Avenida Calidad Nr.4  
Parque, Industrial Internacional  
Tijuana  
22425  
Mexic

**Fabricatie**

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

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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:

### 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

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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

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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 ASD Inc.  
 6250 Shier Rings Road  
 Dublin  
 Ohio  
 43016  
 USA

**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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# Certificat CE - Sistem Integral de Asigurare a Calitatii

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

## Lista subcontractantilor majori

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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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# 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:****Servicii prestate**

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

**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

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

**Subcontractant:****Servicii prestate**

Sterigenics US, LLC  
344 Bonnie Circle  
Corona  
California  
92880  
USA

**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**  
Data: **2017-06-28**  
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

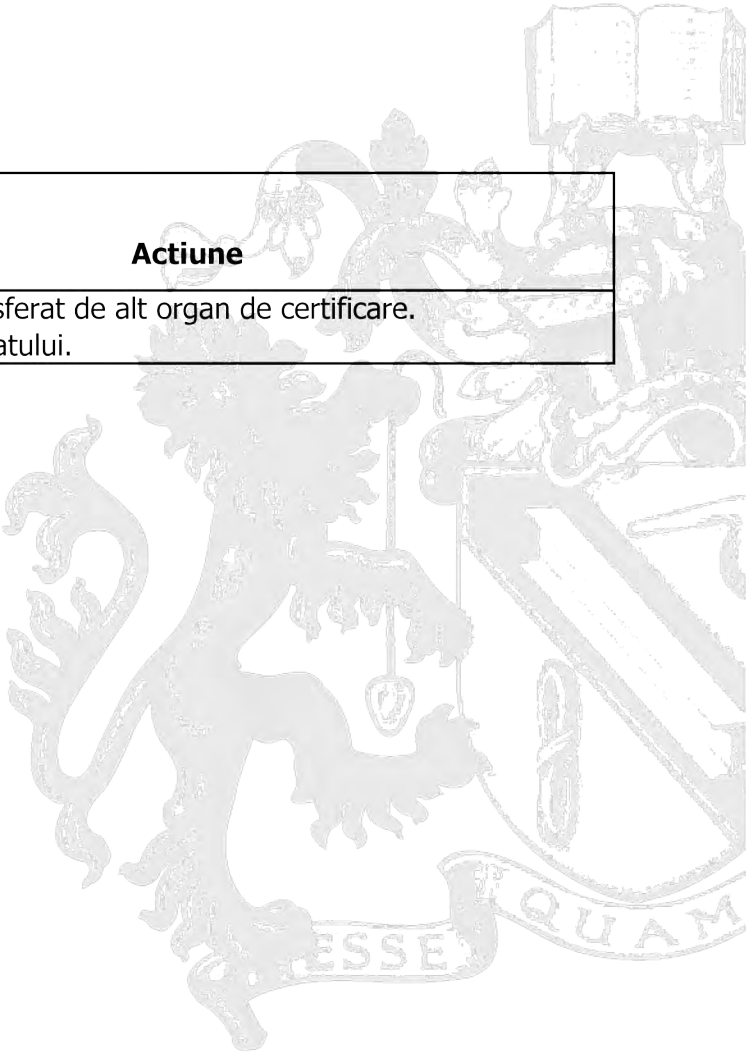
### Furnizor crucial

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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. |



Valabilitatea prezentului certificat este conditionata de mentinerea sistemului nde 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.



\*\*\*\*\*

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

# EC Design-Examination Certificate

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

**No.****CE 661326****Issued To:**

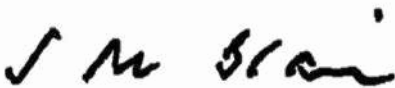
**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

In respect of:

**Cardiothoracic Catheters.**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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 3

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 certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 661326

Issued To:

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

| Product Description                                   | Product Code    |
|-------------------------------------------------------|-----------------|
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 10F | 200/810/100     |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 12F | 200/810/120     |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 16F | 200/810/160     |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 20F | 200/810/200     |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 24F | 200/810/240     |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 28F | 200/810/280     |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 32F | 200/810/320     |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 36F | 200/810/360     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 10F   | 200/812/100     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 12F   | 200/812/120     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 16F   | 200/812/160     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 20F   | 200/812/200     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 24F   | 200/812/240     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 28F   | 200/812/280     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 32F   | 200/812/320     |
| Thoracic Catheter, Angled, Soft, Radio-Opaque – 36F   | 200/812/360     |
| Thoracic Catheter, Straight, Radio-Opaque – 16F       | 200/815/160     |
| Thoracic Catheter, Straight, Radio-Opaque – 20F       | 200/815/200     |
| Thoracic Catheter, Straight, Radio-Opaque – 24F       | 200/815/240     |
| Thoracic Catheter, Straight, Radio-Opaque – 28F       | 200/815/280     |
| Thoracic Catheter, Straight, Radio-Opaque – 32F       | 200/815/320     |
| Thoracic Catheter, Straight, Radio-Opaque – 36F       | 200/815/360     |
| Thoracic Catheter, Angled, Radio-Opaque – 32F         | 200/81/320      |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 28F | 209/810/280/700 |
| Thoracic Catheter, Straight, Soft, Radio-Opaque – 32F | 209/810/320/700 |

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

Date: **2017-06-28**

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

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Page 2 of 3

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 certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 661326

Issued To:

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

## Certificate History

| Date    | Reference Number | Action                                              |
|---------|------------------|-----------------------------------------------------|
| Current | 10166350         | First issue. Transferred from another Notified Body |

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

Date: **2017-06-28**

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

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Page 3 of 3

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 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 de examinare a proiectului

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

Nr. **CE 661326**  
Titular: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

Obiectul certificatului:

**Catetere cardiotoracice.**

BSI a examinat dispozitivele de mai sus conform cerintelor Directivei Consiliului 93/42/CEE, Anexa II, Secțiunea 4. Proiectul indeplinește cerințele Directivei. Pentru lansarea pe piață a acestor produse, este necesar certificatul menționat în Anexa II, excluzând Secțiunea 4.

Pentru și în numele BSI, organ de certificare în acceptiunea sus-menționatei Directive (Organ de certificare cu numărul 0086):



Stewart Brain, Șef compartiment conformitate și risc  
Dispozitive medicale

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

Data: **2017-06-28**

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Data expirării: **2022-06-27**

Pagina 1 din 3

Valabilitatea prezentului certificat este condiționată de menținerea sistemului de calitate la cerințele Directivei dovedită de organul de certificare care supraveghează compania. Prezentă aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte on în numele companiei care deține prezentul certificat, cu excepția unui acord contrar, încheiat cu BSI. Prezentul certificat a fost redactat electronic și este condiționat de respectarea caietului de sarcini.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 în 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.

# Certificat CE de examinare a proiectului

## Informatii suplimentare pentru CE 661326

Titular:

**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

| Descriere produs                                  | Cod produs      |
|---------------------------------------------------|-----------------|
| Cateter toracic, drept, moale, radio-opac- 10F    | 200/810/100     |
| Cateter toracic, drept, moale, radio-opac- 12F    | 200/810/120     |
| Cateter toracic, drept, moale, radio-opac- 16F    | 200/810/160     |
| Cateter toracic, drept, moale, radio-opac- 20F    | 200/810/200     |
| Cateter toracic, drept, moale, radio-opac- 24F    | 200/810/240     |
| Cateter toracic, drept, moale, radio-opac- 28F    | 200/810/280     |
| Cateter toracic, drept, moale, radio-opac- 32F    | 200/810/320     |
| Cateter toracic, drept, moale, radio-opac- 36F    | 200/810/360     |
| Cateter toracic, in unghi, moale, radio-opac- 10F | 200/812/100     |
| Cateter toracic, in unghi, moale, radio-opac- 12F | 200/812/120     |
| Cateter toracic, in unghi, moale, radio-opac- 16F | 200/812/160     |
| Cateter toracic, in unghi, moale, radio-opac- 20F | 200/812/200     |
| Cateter toracic, in unghi, moale, radio-opac- 24F | 200/812/240     |
| Cateter toracic, in unghi, moale, radio-opac- 28F | 200/812/280     |
| Cateter toracic, in unghi, moale, radio-opac- 32F | 200/812/320     |
| Cateter toracic, in unghi, moale, radio-opac- 36F | 200/812/360     |
| Cateter toracic, drept, radio-opac- 16F           | 200/815/160     |
| Cateter toracic, drept, radio-opac- 20F           | 200/815/200     |
| Cateter toracic, drept, radio-opac- 24F           | 200/815/240     |
| Cateter toracic, drept, radio-opac- 28F           | 200/815/280     |
| Cateter toracic, drept, radio-opac- 32F           | 200/815/320     |
| Cateter toracic, drept, radio-opac- 36F           | 200/815/360     |
| Cateter toracic, in unghi, radio-opac-32F         | 200/81/320      |
| Cateter toracic, drept, moale, radio-opac- 28F    | 209/810/280/700 |
| Cateter toracic, drept, moale, radio-opac- 32F    | 209/810/320/700 |

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

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Pagina 2 din 3

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 CE de examinare a proiectului

Informatii suplimentare pentru CE 661326

Titular:

Smiths Medical International Ltd.  
Boundary Road  
Hythe  
Kent  
CT21 6JL  
Marea Britanie

## Istoricul Certificatului

| Data    | Numar de referinta | Actiune                                                  |
|---------|--------------------|----------------------------------------------------------|
| Curenta | 10166350           | Prima editie. Transferat de un alt organ de certificare. |

Prima editie: 2017-06-28

Data: 2017-06-28

Data expirarii: 2022-06-27

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului nde 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.  
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Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A  
membra a grupului BSI.

\*\*\*\*\*

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

# EC Certificate - Production Quality Assurance

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

**No.****CE 661328****Issued To:**

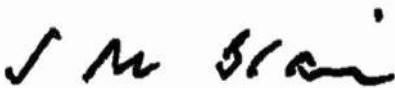
**Smiths Medical International Ltd.  
Boundary Road  
Hythe  
Kent  
CT21 6JL  
United Kingdom**

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 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 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 661328

## Certificate Scope:

### **The manufacture and final inspection of sterile:**

**Drainage Devices, Obstetrics and Gynaecology Devices, Oxygen and Humidity Management Devices, Intubation Systems, Infusion Disposables, Feeding Devices Accessories**

### **The manufacture and final inspection of non-sterile:**

**Resuscitation Devices, Tracheostomy Tubes, Intubation Systems**

**Those aspects of annex V relating to the securing and maintaining of sterility of Vascular Access Device Accessories, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology 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.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Production Quality Assurance

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:

Certificate No: **CE 661328**  
 Date: **2017-06-28**  
 Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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

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# EC Certificate - Production Quality Assurance

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:

Certificate No: **CE 661328**  
Date: **2017-06-28**  
Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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

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# EC Certificate - Production Quality Assurance

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:

Certificate No: **CE 661328**  
 Date: **2017-06-28**  
 Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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

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# EC Certificate - Production Quality Assurance

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:

Certificate No: **CE 661328**  
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.<br>10 Bowman Dr.<br>Keene<br>New Hampshire<br>03431<br>USA           | Manufacture         |
| Smiths Medical ASD Inc.<br>1265 Grey Fox Road<br>St Paul<br>Minnesota<br>55112<br>USA        | Manufacture         |
| Smiths Medical ASD Inc.<br>201 West Queen St.,<br>Southington<br>Connecticut<br>06489<br>USA | Manufacture         |

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# EC Certificate - Production Quality Assurance

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

## 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 ASD Inc.<br>6250 Shier Rings Road<br>Dublin<br>Ohio<br>43016<br>USA                  | Manufacture         |
| Smiths Medical ASD Inc.<br>9124 Polk Lane, Suite 101<br>Olive Branch<br>Mississippi<br>38654<br>USA | Distribution        |
| Smiths Medical Czech Republic a.s.<br>Olomoucká 306<br>753 01 Hranice<br>Czech Republic             | Manufacture         |

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# EC Certificate - Production Quality Assurance

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

## 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<br>5700 W 23rd Ave<br>Gary<br>Indiana<br>46406<br>USA                                 | Manufacture         |
| Smiths Medical International Ltd<br>52 Grayhill Rd<br>Cumbernauld<br>Glasgow<br>G68 9HQ<br>United Kingdom | Manufacture         |
| Smiths Medical International<br>Nijmegen<br>Bijsterhuizen 22-08<br>6604 LD Wijchen<br>The Netherlands     | Distribution        |

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# EC Certificate - Production Quality Assurance

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

## List of Significant Subcontractors

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Certificate No: **CE 661328**  
 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<br>Via della Stazione, 2<br>Latina Scalo<br>04100<br>Italy                                                   | Packaging           |
| Sterigenics Belgium<br>(Petit-Rechain) SA<br>Zoning Industriel de Petit-Rechain<br>Avenue Andre Ernst 21<br>B-4800 Verviers<br>Belgium | ETO Sterilization   |
| Sterigenics UK Limited<br>Cotes Park Estate<br>Somercoates<br>Alfreton<br>DE55 4NJ<br>United Kingdom                                   | ETO Sterilization   |

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# EC Certificate - Production Quality Assurance

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

## 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 |
|---------------------------------------------------------------------------------------------------------|---------------------|
| Sterigenics US, LLC<br>344 Bonnie Circle<br>Corona<br>California<br>92880<br>USA                        | Gamma Sterilization |
| Sterigenics, LLC<br>1700 College Blvd.<br>West Memphis<br>Arkansas<br>72301<br>USA                      | Gamma Sterilization |
| Sterilization Services of<br>Tennessee, Inc<br>2396 Florida Street<br>Memphis<br>Tennessee 38109<br>USA | ETO Sterilization   |

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# EC Certificate - Production Quality Assurance

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:

Certificate No: **CE 661328**  
 Date: **2017-06-28**  
 Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

| Subcontractor:                                                                                                                        | Service(s) supplied |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| UPG<br>Avenida La Cuspide #1<br>Parque Industrial Tecnomex<br>Del. Playas de Tijuana<br>Tijuana<br>Baja California<br>22700<br>Mexico | Manufacture         |
| Velcro USA Inc.<br>95 Sundial Avenue<br>Manchester<br>New Hampshire<br>03103-7206<br>USA                                              | Crucial Supplier    |

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# EC Certificate - Production Quality Assurance

## Certificate History

Certificate No: **CE 661328**  
Date: **2017-06-28**  
Issued To: **Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

| Date    | Reference Number   | Action                                                                       |
|---------|--------------------|------------------------------------------------------------------------------|
| Current | 8693885<br>8603164 | 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.



By Royal Charter

Traducere din limba engleză

## Certificat CE – Asigurarea Calității Producției

Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Nr. **CE 661328**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

Cu privire la:

**Vedeți domeniul de certificare pe cealaltă pagină.**

În baza examinării efectuate de noi cu privire la sistemul de asigurare a calității conform cerințelor Directivei Consiliului 93/42/CEE, Anexa V. Sistemul de asigurare a calității îndeplinește cerințele directivei. Pentru plasarea pe piață a produselor clasa IIb și clasa III este necesar un certificat Anexa III.

Pentru și în numele BSI, Organism de Notificare pentru Directiva de mai sus (Număr Organism de Notificare 0086):

Semnătura – indescifrabilă

**Stewart Brain**, Director Conformitate și Risc  
Dispozitive Medicale

Prima emitere: **28-06-2017**

Data: **28-06-2017**

Data expirării: **27-06-2022**

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Pagina 1 din 2

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat Nr.: CE 661328**

**Domeniu Certificat:**

**Fabricarea și inspecția finală a următoarelor produse sterile:**

**Dispozitive Drenaj, Dispozitive pentru Obstetrică și Ginecologie, Dispozitive Management Oxigen și Umiditate, Sisteme de Intubare, Dispozitive de Perfuzie de Unică Folosință, Accesorii Dispozitive pentru Alimentare.**

**Fabricarea și inspecția finală a următoarelor produse non-sterile:**

**Dispozitive de Resuscitare, Tuburi Traheostomie, Sisteme de Intubare.**

**Acele aspecte din Anexa V cu privire la securitatea și menținerea sterilității Accesoriiilor pentru Dispozitivele de Acces Vascular, Dispozitive de Perfuzie de Unică Folosință, Sisteme de Intubare, Dispozitive pentru Obstetrică și Ginecologie.**

Prima emitere: **28-06-2017**

Data: **28-06-2017**

Data expirării: **27-06-2022**

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Pagina 2 din 2

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

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Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

| <b>Subantreprenor</b>                                                                                           | <b>Servicii furnizate</b> |
|-----------------------------------------------------------------------------------------------------------------|---------------------------|
| Brightwake Limited<br>Lowmoor Business Park<br>Kirby-in-Ashfield<br>Nottinghamshire<br>NG17 7JZ<br>Regatul Unit | Fabricare                 |
| GaleMed Corporation<br>Nr. 87, Li-Gong 2nd Road<br>Wu-Jia<br>YILAN 268<br>Taiwan                                | Fabricare                 |
| GE Medical<br>Pollards Wood<br>Nightingales Lane<br>Chalfont Saint Giles<br>HP8 4SP<br>Regatul Unit             | Fabricare                 |

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Pagina 1 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

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Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

| <b>Subantreprenor</b>                                                                                                      | <b>Servicii furnizate</b> |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Koo Medical Equipment (Shanghai) Co. Ltd.<br>100 Zhongde Road Dakun Industrial Park<br>Songjiang, Shanghai 201614<br>China | Fabricare                 |

---

|                                                                                       |                    |
|---------------------------------------------------------------------------------------|--------------------|
| Pentair Filtration Solutions<br>1350 Hammond Road, St. Paul<br>Minnesota 55110<br>SUA | Furnizor Principal |
|---------------------------------------------------------------------------------------|--------------------|

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|                                                                                                 |           |
|-------------------------------------------------------------------------------------------------|-----------|
| Quadrant EPP Belgium N.V.<br>Industriepark Noord Robert Tavernierlaan 2<br>Tielt 8700<br>Belgia | Fabricare |
|-------------------------------------------------------------------------------------------------|-----------|

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Pagina 2 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

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Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

**Subantreprenor**

**Servicii furnizate**

Smiths Healthcare Manufacturing SA de CV    Fabricare  
Avenida Calidad Nr. 4 Parque,  
Industrial Internacional Tijuana  
22425  
Mexic

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Smiths Healthcare Manufacturing SA de CV    Fabricare  
Carretera Miguel Aleman km 21.7 Parque  
Industrial Monterrey Apodaca  
Nuevo Leon 66603  
Mexic

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Pagina 3 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

**Subantreprenor**

**Servicii furnizate**

Smiths Medical ASD Inc. 10 Bowman Dr. Fabricare  
Keene, New Hampshire, 03431  
SUA

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Smiths Medical ASD Inc., 1265 Grey Fox Road, St. Paul, Minnesota 55112  
Fabricare  
SUA

---

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

---

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Pagina 4 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

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Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

| <b>Subantreprenor</b>                                                     | <b>Servicii furnizate</b> |
|---------------------------------------------------------------------------|---------------------------|
| Smiths Medical ASD Inc., 6250 Shier Rings Road, Dublin, Ohio 43016<br>SUA | Fabricare                 |

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Pagina 5 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

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Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

| <b>Subantreprenor</b>                                                                                  | <b>Servicii furnizate</b> |
|--------------------------------------------------------------------------------------------------------|---------------------------|
| Smiths Medical Gary, 5700 W 23rd Ave<br>Gary, Indiana 46406<br>SUA                                     | Fabricare                 |
| Smiths Medical International Ltd., 52<br>Grayhill Rd., Cumbernauld, Glasgow G68<br>9HQ<br>Regatul Unit | Fabricare                 |
| Smiths Medical International Nijmegen<br>Bijsterhuizen 22-08, 6604 LD Wijchen<br>Olanda                | Distribuție               |

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Pagina 6 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

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Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

| <b>Subantreprenor</b>                                                                      | <b>Servicii furnizate</b> |
|--------------------------------------------------------------------------------------------|---------------------------|
| Smiths Medical Italia Srl, Via della Stazione, Ambalare<br>2 Latina Scalo, 04100<br>Italia |                           |

---

|                                                                                                                                      |                 |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Sterigenics Belgium (Petit-Rechain) SA<br>Zoning Industriel de Petit-Rechain, Avenue<br>Andre Ernst 21, B-4800<br>Verviers<br>Belgia | Sterilizare ETO |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------|

---

|                                                                                                |                 |
|------------------------------------------------------------------------------------------------|-----------------|
| Sterigenics UK Limited, Cotes Park Estate,<br>Somercotes Alfreton,<br>DE55 4NJ<br>Regatul Unit | Sterilizare ETO |
|------------------------------------------------------------------------------------------------|-----------------|

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Pagina 7 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

| <b>Subantreprenor</b>                                                        | <b>Servicii furnizate</b> |
|------------------------------------------------------------------------------|---------------------------|
| Sterigenics US, LLC 344 Bonnie Circle,<br>Corona,<br>California 92880<br>SUA | Sterilizare Gamma         |

---

|                                                                                |                   |
|--------------------------------------------------------------------------------|-------------------|
| Sterigenics LLC, 1700 College Blvd., West<br>Memphis,<br>Arkansas 72301<br>SUA | Sterilizare Gamma |
|--------------------------------------------------------------------------------|-------------------|

---

|                                                                                                       |                 |
|-------------------------------------------------------------------------------------------------------|-----------------|
| Sterilization Services of Tennessee, Inc.,<br>2396 Florida Street, Memphis,<br>Tennessee 38109<br>SUA | Sterilizare ETO |
|-------------------------------------------------------------------------------------------------------|-----------------|

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Pagina 8 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI  
Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





**Certificat CE – Asigurarea Calității Producției**  
Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

**Lista Principalilor Subantreprenori**

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

**Subantreprenor**

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

**Servicii furnizate**

---

Velcro USA Inc., 95 Sundial Avenue, Furnizor principal  
Manchester,  
New Hampshire 03103-7206  
SUA

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Pagina 9 din 9

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK  
Membră a Grupului de Societăți BSI.





## Certificat CE – Asigurarea Calității Producției

### Istoric Certificat

Certificat Nr.: **CE 661328**  
Data: **28-06-2017**  
Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

| Data    | Număr<br>Referință | Acțiune                                                                                 |
|---------|--------------------|-----------------------------------------------------------------------------------------|
| Curentă | 8693885<br>8603164 | Prima emitere. Transferat de la un alt Organism de Notificare.<br>Reînnoire certificat. |

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Pagina 1 din 1

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

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Traducător autorizat  
Nr. 2769/2015



# Certificate of Registration



# Intertek

This is to certify that the quality management system of

## SMITHS MEDICAL INTERNATIONAL LIMITED

Boundary Road, Hythe, Kent, CT21 6JL, UK

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

### EN ISO 13485:2012

The quality management system is applicable to:

Design of:

Breathing Systems, Drainage Devices, Feeding Devices,  
Filtration Devices, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology  
Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Devices,  
Respiratory Mechanics Devices, Resuscitation Devices,  
Suction Catheters, Tracheostomy Tubes, Vascular Access Devices, Cardio Thoracic  
Catheters and Drapes

Additional Site:

Human Resources and Training, Shipping, Demand Planning, Post Market Surveillance,  
Market Intelligence, E-Business, International Customer Services, Business Development,  
Registrations, Finance, Wallace Women's Healthcare

|                                    |                        |
|------------------------------------|------------------------|
| <b>Certificate Number:</b>         | <b>053-01 B</b>        |
| <b>Initial Certification Date:</b> | <b>20 October 2005</b> |
| <b>Certificate Effective Date:</b> | <b>23 July 2016</b>    |
| <b>Certificate Expiry Date:</b>    | <b>22 July 2019</b>    |



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*Brian Johnson*

*AMTAC Certification Services Limited, Milton Keynes, UK*

*This certificate is the property of AMTAC Certification Services Ltd*

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# Intertek



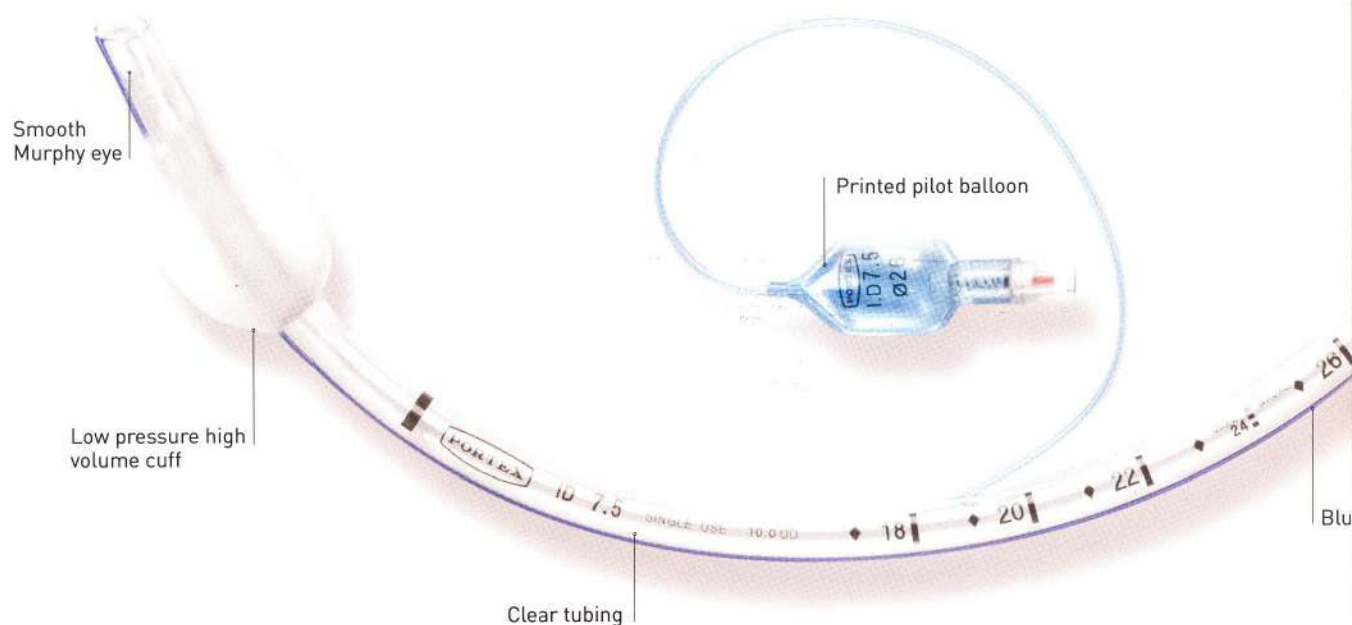
**Portex® Choice Tracheal Tubes for the Operating Room**  
**Affordable quality - SMILE!**



**AIRWAY MANAGEMENT**

**PORTEX**

TM



## The New Portex® Tracheal Tube

**Smiths Medical, a leading global provider of medical devices, is pleased to announce the launch of the new Portex® Tracheal Tube.**

**The new Portex® Tracheal Tube is the first choice tube for everyday intubation, meeting all the clinical requirements expected of a short-term tube for the operating room.**

### Affordable quality

Portex®, a renowned brand in airway products, has created a high quality tracheal tube that incorporates all the superior features expected from a Smiths Medical product, yet at an affordable price.

The new Portex® Tracheal Tube is perfect for the majority of all operating room procedures of a short duration.

### Low pressure seal

The new Portex® Tracheal Tube has a low pressure, high volume barrel cuff, reducing the risk of creasing on inflation and in turn minimising the pressure on the tracheal wall.

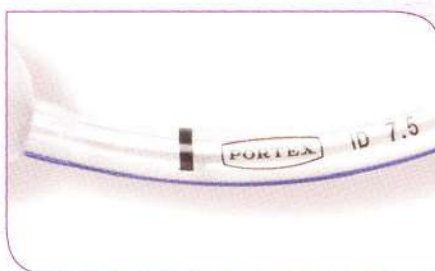
The large cuff resting diameter relieves the pressure on the tracheal wall ensuring patient safety and comfort.

Blue 15mm connector

Radio-opaque line



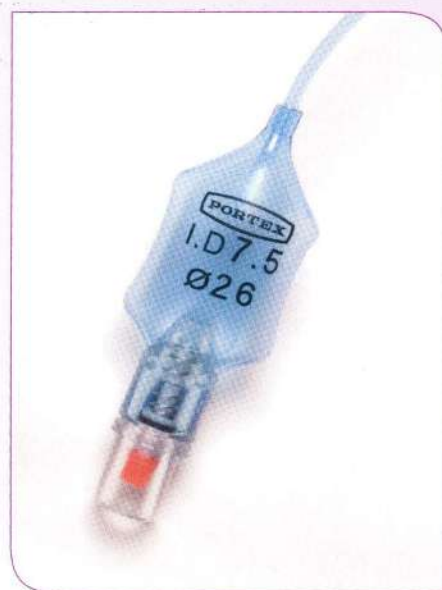
Low pressure high volume cuff



Intubation depth marker



Smooth Murphy eye



Printed pilot balloon

## Superior smooth finish

Unlike some competitor tubes that contain a sharp, cold cut edge to the Murphy eye, the new Portex® Tracheal tube contains a smooth and polished Murphy eye.

It also has been smoothed and fully blended to the cuff edge to minimise the risk of trauma to the patient during intubation.

## Easily identifiable

A blue radio-opaque line can be seen on the full length of the new Portex® Tracheal Tube to allow the verification of tube positioning within the patient via X-ray.

The tube is made out of clear, implant-tested PVC, therefore correct intubation is confirmed when the tube 'mists'.

All markings on the tube are clearly printed and include an intubation depth marker, vocal cord distal markings and an oral/nasal cut line.

## Fully informed

The new Portex® Tracheal tube incorporates a smooth edged pilot balloon that displays the size and maximum inflation pressure allowing for the relevant size to be identified, even when in situ. The balloon changes shape when inflated and contains a central channel so it will not collapse if the cuff needs to be deflated quickly in an emergency situation.

The inflation line is blue to reduce the risk of being accidentally cut.

## Portex® Choice Tracheal Tube

For short-term intubation within the operating room

### ORDERING INFORMATION

| Product Code | I.D.(mm) | O.D.(mm) | Cuff resting diam.(mm) | Pack Qty |
|--------------|----------|----------|------------------------|----------|
| 100/150/050  | 5.0      | 6.7      | 22                     | 10       |
| 100/150/055  | 5.5      | 7.3      | 22                     | 10       |
| 100/150/060  | 6.0      | 8.0      | 24                     | 10       |
| 100/150/065  | 6.5      | 8.5      | 24                     | 10       |
| 100/150/070  | 7.0      | 9.2      | 26                     | 10       |
| 100/150/075  | 7.5      | 10.0     | 26                     | 10       |
| 100/150/080  | 8.0      | 10.7     | 28                     | 10       |
| 100/150/085  | 8.5      | 11.3     | 28                     | 10       |
| 100/150/090  | 9.0      | 12.0     | 30                     | 10       |
| 100/150/095  | 9.5      | 12.7     | 30                     | 10       |

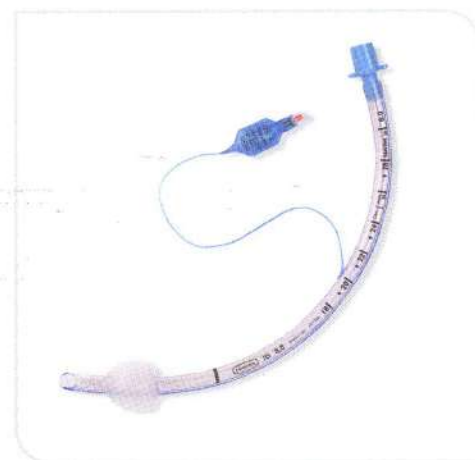


## Portex® Soft Seal® Tracheal Tube

For long-term intubation and short-term ICU stays ( up to 2 days)

### ORDERING INFORMATION

| Product Code | I.D.(mm) | O.D.(mm) | Cuff resting diam.(mm) | Pack Qty |
|--------------|----------|----------|------------------------|----------|
| 100/199/050  | 5.0      | 6.9 mm   | 25                     | 20       |
| 100/199/055  | 5.5      | 7.6 mm   | 28                     | 20       |
| 100/199/060  | 6.0      | 8.2 mm   | 29                     | 20       |
| 100/199/065  | 6.5      | 8.9 mm   | 30                     | 20       |
| 100/199/070  | 7.0      | 9.6 mm   | 31                     | 20       |
| 100/199/075  | 7.5      | 10.3 mm  | 32                     | 20       |
| 100/199/080  | 8.0      | 10.9 mm  | 33                     | 20       |
| 100/199/085  | 8.5      | 11.6 mm  | 33                     | 20       |
| 100/199/090  | 9.0      | 12.3 mm  | 33                     | 20       |
| 100/199/095  | 9.5      | 13.0 mm  | 33                     | 20       |



## Portex® Suction Above The Cuff Tracheal Tube (SACETT™)

For all ICU patients over 2 days to help reduce the risk of V.A.P

### ORDERING INFORMATION

| Product Code | I.D.(mm) | O.D.(mm) | Cuff resting diam.(mm) | Pack Qty |
|--------------|----------|----------|------------------------|----------|
| 100/189/060  | 6.0      | 9.0      | 23                     | 10       |
| 100/189/065  | 6.5      | 9.7      | 23                     | 10       |
| 100/189/070  | 7.0      | 10.4     | 30                     | 10       |
| 100/189/075  | 7.5      | 11.1     | 30                     | 10       |
| 100/189/080  | 8.0      | 11.9     | 30                     | 10       |
| 100/189/085  | 8.5      | 12.4     | 30                     | 10       |
| 100/189/090  | 9.0      | 12.8     | 30                     | 10       |



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