

# EC Certificate - Full Quality Assurance System

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

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

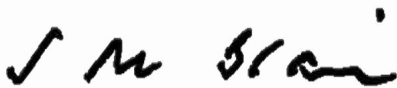
**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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

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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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**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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**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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**Hythe**  
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**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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**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

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**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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**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>Somercotes<br>Alfreton<br>DE55 4NJ<br>United Kingdom                                    | ETO Sterilization   |

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**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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**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**  
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**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 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 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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# 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

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

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**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

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**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

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**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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**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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**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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**CT21 6JL**  
**Marea Britanie**

### Subcontractant:

### Servicii prestate

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

**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

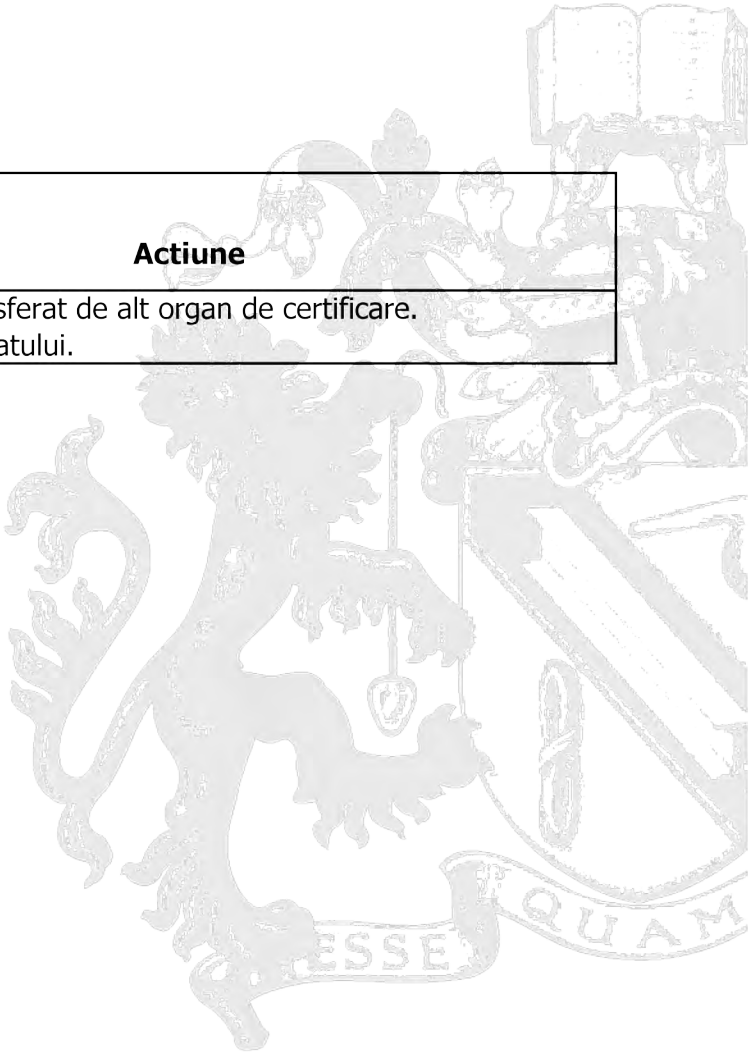
**Furnizor crucial**

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

Certificat nr.: **CE 661325**  
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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:**

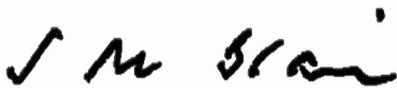
**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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 îndeplinește 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 accepțiunea 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 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.

# 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.  
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 Certificate - Production Quality Assurance

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

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

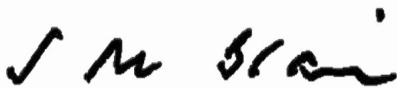
**Smiths Medical International Ltd.  
Boundary Road  
Hythe  
Kent  
CT21 6JL  
United Kingdom**

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                     | <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 - 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

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>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

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 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

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 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

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 |
|---------------------------------------------------------------------------------------------------------|---------------------|
| 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

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**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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**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                 |

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|                                                                                       |                    |
|---------------------------------------------------------------------------------------|--------------------|
| 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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**Kent**  
**CT21 6JL**  
**Regatul Unit**

**Subantreprenor**

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

**Servicii furnizate**

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

**Subantreprenor**

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

**Servicii furnizate**

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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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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  
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**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  
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**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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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  
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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 Italia Srl, Via della Stazione, 2 Latina Scalo, 04100 Italia | Ambalare                  |

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

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

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**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         |

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|                                                                                |                   |
|--------------------------------------------------------------------------------|-------------------|
| 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.





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**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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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  
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## 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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\*\*\*\*\*

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

Traducător autorizat  
Nr. 2769/2015



# Certificate of Registration

The Intertek logo is a dark blue rounded rectangle with the word "Intertek" in white, bold, sans-serif font.

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>    |



061

A black ink signature of Brian Johnson, consisting of a stylized 'B' followed by a horizontal line.

*Brian Johnson*

*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. AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited. AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061. In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.



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