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 devices(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

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

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 agreat. 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 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 limitate la termenii și condițiile acordului. AMTAC nu își asumă responsabilitatea față de oricare parte alta decât Clientul în conformitate cu acordul, pentru nicio pierdere, cheltuială sau daună ocazionate prin utilizarea acestui Certificat. Clientul este singurul autorizat pentru a permite reproducerea sau distribuirea 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 Organsim Notificat conform Directivei 93/42/CEE pentru dispozitivele medicale, cu număr de identificare 0473.

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

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

Certificate Number:
119-04 C

Initial Certification Date:
08 June 2004

Date of Certification Decision:
25 June 2018

Issuing Date:
25 June 2018

Valid Until:
24 June 2021

This is to certify that the management system of:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

See appendix for additional sites and additional site scopes

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

EN ISO 13485:2016

The management system is applicable to:

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

The Servicing of active medical devices.

UKAS MANAGEMENT SYSTEMS
061

Calin Moldovean
President, Business Assurance

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

"This certificate is the property of AMTAC Certification Services Ltd a wholly owned subsidiary of Intertek Holdings Ltd"

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

Traducere din limba engleză

CERTIFICAT DE ÎNREGISTRARE

Se certifică prin prezenta că sistemul de management al:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germania

Pentru locații și domenii suplimentare, vedeți anexa

a fost înregistrată de către Intertek deoarece se conformează cerințelor:

EN ISO 13485:2016

Certificat Număr:
119-04 C

Data Certificării Inițiale:
08 Iunie 2004

Data Deciziei Certificării:
25 Iunie 2018

Data Emiterii:
25 Iunie 2018

Valabil Până la:
24 Iunie 2021

061

Sistemul de management este aplicabil pentru:

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

Service-ul dispozitivelor medicale active.

Semnătura - indescifrabilă
Calin Moldovean
Președinte, Business Assurance

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

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

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

****

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

Traducător autorizat
Nr. 2769/2015

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

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

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

EC Certificate - Full Quality Assurance System

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

No. **CE 661325**

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

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-06-28** Date: **2017-06-28** Expiry Date: **2022-06-27**

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Certificate No: CE 661325

Certificate Scope:

The design, development and manufacture of sterile:

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

The design, development and manufacture of non-sterile:

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

First Issued: **2017-06-28** Date: **2017-06-28** Expiry Date: **2022-06-27**

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

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

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EC Certificate - Full Quality Assurance System

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

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**
Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4 Parque, Industrial Internacional Tijuana 22425 Mexico	**Manufacture**
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	**Manufacture**

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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**
Smiths Medical ASD Inc. 10 Bowman Dr. Keene New Hampshire 03431 USA	**Manufacture**
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	**Manufacture**
Smiths Medical ASD Inc. 201 West Queen St., Southington Connecticut 06489 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

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

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

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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EC Certificate - Full Quality Assurance System

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

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

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics, LLC 1700 College Blvd. West Memphis Arkansas 72301 USA	**Gamma Sterilization**
Sterilization Services of Tennessee, Inc 2396 Florida Street Memphis Tennessee 38109 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**
UPG Avenida La Cuspide #1 Parque Industrial Tecnomex Del. Playas de Tijuana Tijuana Baja California 22700 Mexico	**Manufacture**
Velcro USA Inc. 95 Sundial Avenue Manchester New Hampshire 03103-7206 USA	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 661325**

Date: **2017-06-28**

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

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

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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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MUSUROIA MIRELA

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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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
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 prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
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 prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
Smiths 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	**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 prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
Smiths Medical ASD Inc. 10 Bowman Dr. Keene New Hampshire 03431 USA	**Fabricatie**
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	**Fabricatie**
Smiths Medical ASD Inc. 201 West Queen St., Southington Connecticut 06489 USA	**Fabricatie**

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
Smiths Medical 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	**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 prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
Smiths Medical Gary 5700 W 23rd Ave Gary Indiana 46406 USA	**Fabricatie**
Smiths Medical International Ltd 52 Grayshill 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 prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
Smiths Medical 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

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
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 prestatiile aferente produsului certificat prin:

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

Subcontractant:	**Servicii prestate**
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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By Royal Charter

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 8603169	Prima editie. Transferat de alt organ de certificare. Reinnoirea certificatului.

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MINISTERUL JUSTITIEI
MUSUROIA MIRELA
Legitimație nr. 2769
TRADUCĂTOR AUTORIZAT

****

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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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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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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Certificat CE de examinare a proiectului

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II Sectiunea 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, Sectiunea 4. Proiectul indeplineste cerintele Directivei. Pentru lansarea pe piata a acestor produse, este necesar certificatul mentionat in Anexa II, excluzand 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**

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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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**

****

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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By Royal Charter

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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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 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 - 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) Co., Ltd 100 Zhongde Road Dakun Industrial Park Songjiang, Shanghai 201614 China	**Manufacture**
Pentair Filtration Solutions 1350 Hammond Road St. Paul Minnesota 55110 USA	**Crucial Supplier**
Quadrant EPP Belgium N.V. Industriepark Noord Robert Tavernierlaan 2 Tielt 8700 Belgium	**Manufacture**

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EC Certificate - 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 SA de CV Avenida Calidad No.4 Parque, Industrial Internacional Tijuana 22425 Mexico	**Manufacture**
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	**Manufacture**

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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. 10 Bowman Dr. Keene New Hampshire 03431 USA	**Manufacture**
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	**Manufacture**
Smiths Medical ASD Inc. 201 West Queen St., Southington Connecticut 06489 USA	**Manufacture**

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EC Certificate - 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. 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 - 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 5700 W 23rd Ave Gary Indiana 46406 USA	**Manufacture**
Smiths Medical International Ltd 52 Grayshill Rd Cumbernauld Glasgow G68 9HQ United Kingdom	**Manufacture**
Smiths Medical International Nijmegen Bijsterhuizen 22-08 6604 LD Wijchen The Netherlands	**Distribution**

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EC Certificate - 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 Via della Stazione, 2 Latina Scalo 04100 Italy	**Packaging**
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 B-4800 Verviers Belgium	**ETO Sterilization**
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom	**ETO Sterilization**

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EC Certificate - 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 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics, LLC 1700 College Blvd. West Memphis Arkansas 72301 USA	**Gamma Sterilization**
Sterilization Services of Tennessee, Inc 2396 Florida Street Memphis Tennessee 38109 USA	**ETO Sterilization**

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EC Certificate - 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 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 - 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 8603164	First issue. Transferred from another Notified Body. Certificate renewal.

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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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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.

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

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 Accesoriilor 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**

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.

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

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

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
Koo Medical Equipment (Shanghai) Co. Ltd. 100 Zhongde Road Dakun Industrial Park Songjiang, Shanghai 201614 China	Fabricare
Pentair Filtration Solutions 1350 Hammond Road, St. Paul Minnesota 55110 SUA	Furnizor Principal
Quadrant EPP Belgium N.V. Industriepark Noord Robert Tavernierlaan 2 Tielt 8700 Belgia	Fabricare

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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

Subantreprenor	Servicii furnizate
Smiths Healthcare Manufacturing SA de CV Avenida Calidad Nr. 4 Parque, Industrial Internacional Tijuana 22425 Mexic	Fabricare
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman km 21.7 Parque Industrial Monterrey Apodaca Nuevo Leon 66603 Mexic	Fabricare

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. Keene, New Hampshire, 03431 SUA	Fabricare
Smiths Medical ASD Inc., 1265 Grey Fox Road, St. Paul, Minnesota 55112 SUA	Fabricare
Smiths Medical ASD Inc., 201 West Queen St., Southington, Connecticut 06489 SUA	Fabricare

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

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., 6250 Shier Rings Road, Dublin, Ohio 43016 SUA	Fabricare
Smiths Medical ASD Inc., 9124 Polk Lane, Suite 101 Olive Branch, Mississippi 38654 SUA	Distribuție
Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice Republica Cehă	Fabricare

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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

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

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

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 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 Belgia	Sterilizare ETO
Sterigenics UK Limited, Cotes Park Estate, Somercotes Alfreton, DE55 4NJ Regatul Unit	Sterilizare ETO

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Certificat CE – Asigurarea Calității Producției

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

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

Subantreprenor	Servicii furnizate
Sterigenics US, LLC 344 Bonnie Circle, Corona, California 92880 SUA	Sterilizare Gamma
Sterigenics LLC, 1700 College Blvd., West Memphis, Arkansas 72301 SUA	Sterilizare Gamma
Sterilization Services of Tennessee, Inc., 2396 Florida Street, Memphis, Tennessee 38109 SUA	Sterilizare ETO

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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 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
UPG Avenida La Cuspide #1, Parque Industrial Tecnomex Del. Playas de Tijuana, Tijuana, Baja California 22700 Mexic	Producție
Velcro USA Inc., 95 Sundial Avenue, Manchester, New Hampshire 03103-7206 SUA	Furnizor principal

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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 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 Referință	Acțiune
Curentă	8693885 8603164	Prima emitere. Transferat de la un alt Organism de Notificare. Reînnoire certificat.

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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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****

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

Traducător autorizat
Nr. 2769/2015

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

Certificate of Registration

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

Certificate Number:	**053-01 B**
Initial Certification Date:	**20 October 2005**
Certificate Effective Date:	**23 July 2016**
Certificate Expiry Date:	**22 July 2019**

UKAS MANAGEMENT SYSTEMS
061

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

Certificat de Înregistrare

Intertek

Prin prezenta se certifică faptul că sistemul de management al calității al

SMITHS MEDICAL INTERNATIONAL LIMITED

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

a fost evaluat și înregistrat de AMTAC Certification Services Limited ca fiind conform cerințelor:

EN ISO 13485:2012

Sistemul de management al calității este aplicabil pentru:

Proiectarea:
Sistemelor de Respirat, Dispozitivelor de Drenaj, Dispozitivelor de Alimentare, Dispozitivelor de Filtrare, Infuzoare de Unică Folosință, Sisteme de Intubare, Dispozitive de Obstetrică și Ginecologie, Dispozitive de Management al Oxigenului și Umidității, Dispozitive de Monitorizare a Presiunii, Dispozitive Mecanice de Respirație, Dispozitive de Resuscitare, Catetere Sucțiune, Tuburi Traheotomie, Dispozitive Acces Vascular, Catetere Cardio Toracice și Comprese Chirurgicale

Poziții Suplimentare:
Resurse Umane și Pregătire Profesională, Transport, Cerere Planificare, Supraveghere Post Piață, Cunoașterea Pieței, E-Business, Servicii Client Internațional, Dezvolatre Afacere, Înregistrări, Finanțe, Wallace Women's Healthcare

Certificat Număr: Inițial Data	**053-01 B**
Certificării: Dată Efectivă	**20 Octombrie 2005**
Certificat:	**23 Iulie 2016**
Data Expirării Certificatului:	**22 Iulie 2019**

Brian Johnson

UKAS MANAGEMENT SYSTEMS
061

AMTAC Certification Services Limited, Milton Keynes, UK
Acest certificat este proprietatea AMTAC Certification Services Ltd

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Ex. Nr. 2769
TRADUCĂTOR AUTORIZAT
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smiths medical
bringing technology to life

Difficult Airways & Intubation completing the picture

AIRWAY MANAGEMENT

PORTEX™

PORTEX™

Portex® Soft Seal® Laryngeal Mask Range

ORDERING INFORMATION

Description	Size	ID Tube mm	OD Tube mm	MaxCuff Volume ml	Code
Neonates/Infants up to 5kg	1	5.3	7.8	6	**100/220/100**
Infants 5-10kg	1.5	6.1	9.5	8	**100/220/150**
Infants/Children 10-20kg	2	7.1	11.3	12	**100/220/200**
Children 20-30kg	2.5	8.5	13.1	17	**100/220/250**
Children 30-50kg	3	10.1	15.5	25	**100/220/300**
Adults 50-70kg	4	11.0	17.6	35	**100/220/400**
Adults 70kg	5	12.0	19.8	55	**100/220/500**

Portex® Soft Seal® Laryngeal Mask range

Laryngeal Masks are often used as an alternative to a tracheal tube or face mask in short term anaesthesia. It is also becoming more popular for use in difficult airway scenarios or in accident and emergency procedures.

- The Portex® Soft Seal® Laryngeal Mask features the exclusive Soft Seal® Cuff which is less permeable to nitrous oxide[1] than that of reusable masks, reducing increase in pressure and minimising potential trauma.
- The cuff, combined with the higher atrium, helps to provide an improved seal.
- Single Use.
- Better infection control.
- Research has shown that even thoroughly cleaned reusable airway devices still contain residual protein deposits, which have the potential for cross-patient contamination.
- Ease of Access.
- Higher atrium, negating the use of epiglottis bars.
- The Portex® ---Soft Seal® Laryngeal Mask is designed to avoid the risk of blockage without the need for obstructive epiglottis bars, allowing easy access for flexible fibre optic devices and fibre optic guided placement of tracheal tubes.
- The Portex® Soft Seal® Laryngeal Mask has been approved in studies for use in pre-hospital airway management.
- Available in paediatric sizes 1, 1.5, 2 and 2.5.

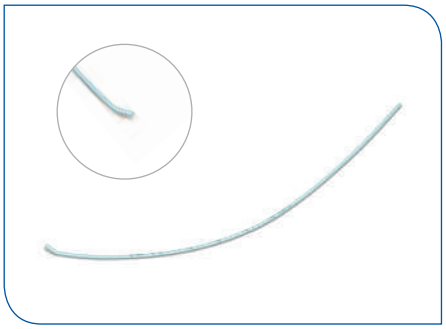
References

1. Van Zundert, A. A. J. et al. Comparison of cuff-pressure changes in LMA-Classic® and the new Soft Seal® laryngeal masks during nitrous oxide anaesthesia in spontaneous breathing patients. European Journal of Anaesthesiology 2004; 21: 547-552.

Introducers, Stylets & Guides

PORTEX® SINGLE USE BOUGIE

Description	OD mm	Length mm	Code
Adult 15Fg	5.0	700	100/123/515

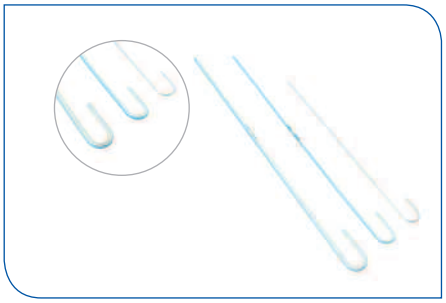


PORTEX® VENN REUSABLE BOUGIE

Description	OD mm	Length mm	Code
Adult 15Fg	5.0	600	14-504-17

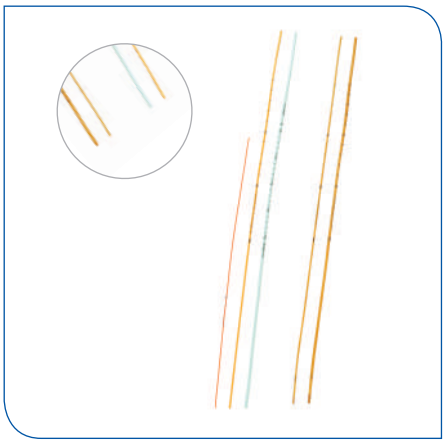
PORTEX® ET TUBE STYLET

Description	Recommended ET Tube Size ID mm	OD mm	Length mm	Code
Large Adult	8.5 - 11.0	5.0	365	100/120/300
Adult	5.0 - 8.0	4.2	335	100/120/200
Paediatric	2.5 - 4.5	2.2	225	100/120/100
Extra Long Large Adult	8.5 - 11.0	5.0	693	100/121/300
Extra Long Adult	5.0 - 8.0	4.0	673	100/121/200



PORTEX® SINGLE USE EXCHANGE GUIDES

Description	OD mm	Length mm	Code
Adult 15Fg	5.0	700	100/123/015
Paediatric 10Ch	3.3	700	100/125/010
Neonatal 5Ch	1.7	500	100/125/005



PORTEX® VENN REUSABLE EXCHANGE GUIDES

Description	OD mm	Length mm	Code
Adult 15Ch	5.0	700	14-504-68
Paediatric 10Ch	3.3	700	14-504-76

Bougies

Bougies are used during intubation of a Difficult Airway as the coudé tip can confirm correct placement through the hold up (clicks) on the tracheal rings.

- Available in 15Fg reusable and single use
- Reusable 600mm - used for over 40 years
- New single use 700mm
- Both have superior memory
- Good flexibility
- Single use will reduce risk of infection

Stylets

Stylets are used to preform a tracheal tube prior to intubation.

- Malleable aluminium adaptation to required shape
- Available in standard and extra long lengths
- Easy insertion and withdrawal
- High density polyurethane coating in neonatal sizes
- Ivory PVC sleeve in adult sizes

Guides

Guides (Exchange Guides) are for when a tracheal tube is exchanged.

- Available in reusable and single use
- New clear marking on Ivory PVC 15Fg Guide
- Polyurethane guides in sizes 10Ch & 5Ch

ET Tube Material

Clear PVC

Siliconised PVC

Ivory PVC

Reinforced PVC

Polyurethane

Profile Soft Seal® Cuff

Reinforced Silicone

Your choice of material

Portex® have a unique range of ET Tube materials to meet almost every anaesthetic requirement. We understand that your choice of material is as important as the design.

- Clear PVC can identify correct intubation through 'misting'
- Siliconised PVC can assist in suctioning in an ICU
- Ivory is soft yet kink resistant for maxilla - facial and nasal intubations
- Polyurethane has no memory so is perfect for uncuffed nasal intubation
- Silicone reinforced for adverse airways
- Single Use PVC reinforced for cervical spinal to reduce the risk of cross infection

Soft Seal® Cuff

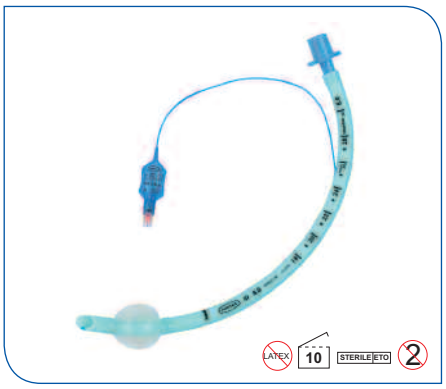
The profile Soft Seal® cuff is made from velvet soft PVC material, giving minimal risk of trauma. Through combining the benefits of the profile cuff design with a larger cuff resting diameter, it ensures an effective seal even when selecting smaller bore tracheal tubes.

- Unique shape ensures minimal contact to the sensitive tracheal mucosa
- Strong yet thin cuffed material reduces the risk of folding and leakage
- Reduced Nitrous Oxide permeability for a more stable cuff pressure

Tracheal Tubes with Profile Soft Seal® Cuff

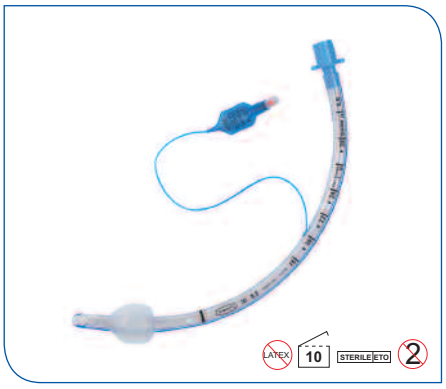
IVORY PVC, NASAL

ID mm	OD mm	Cuff resting Diameter	Code
5.0	7.3	17	100/179/050
5.5	8.0	17	100/179/055
6.0	8.8	23	100/179/060
6.5	9.5	23	100/179/065
7.0	10.2	30	100/179/070
7.5	10.9	30	100/179/075
8.0	11.6	30	100/179/080
8.5	12.4	30	100/179/085
9.0	13.1	30	100/179/090



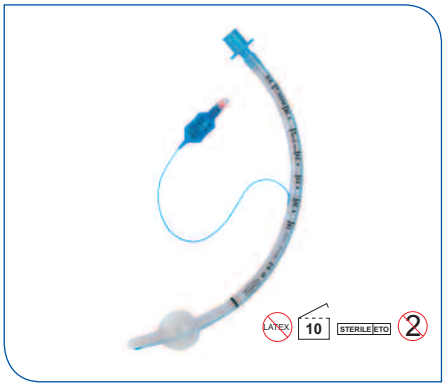
CLEAR PVC, ORAL/NASAL, MURPHY EYE

ID mm	OD mm	Cuff resting Diameter	Code
5.0	6.8	17	100/199/050
5.5	7.4	17	100/199/055
6.0	8.2	23	100/199/060
6.5	8.8	23	100/199/065
7.0	9.6	30	100/199/070
7.5	10.2	30	100/199/075
8.0	11.0	30	100/199/080
8.5	11.6	30	100/199/085
9.0	12.3	30	100/199/090
9.5	13.0	30	100/199/095
10.0	13.7	30	100/199/100



SILICONISED PVC, ORAL/NASAL

ID mm	OD mm	Cuff resting Diameter	Code
5.0	6.8	17	100/166/050
5.5	7.4	17	100/166/055
6.0	8.2	23	100/166/060
6.5	8.8	23	100/166/065
7.0	9.6	30	100/166/070
7.5	10.2	30	100/166/075
8.0	11.0	30	100/166/080
8.5	11.6	30	100/166/085
9.0	12.3	30	100/166/090
9.5	13.0	30	100/166/095
10.0	13.6	32	100/166/100



Tracheal Tubes with Profile Soft Seal® Cuff

The Profile Soft Seal® Cuff combines the benefits of the profile cuff design with a larger cuff resting diameter providing the patient with optimum comfort.

- Minimal contact with the sensitive tracheal mucosa
- Large cuff diameter ensures effective seal
- Reduces movement relative to trachea during ventilation
- When deflated, cuff conforms closely to tube to minimise the risk of trauma during intubation and extubation
- Low pressure - responds rapidly to varying pressures during the respiratory cycle, securing sealing
- Reduces the risk of trauma during intubation and extubation

Every Soft Seal® profile cuffed tube is also equipped with:

- One way valve for efficient and easy inflation and deflation of cuff
- Large pilot balloon clearly shows when cuff is inflated
- An intubation Depth Marker is located 3cm proximal to the cuff to assist in the accurate placement of the tip within the trachea

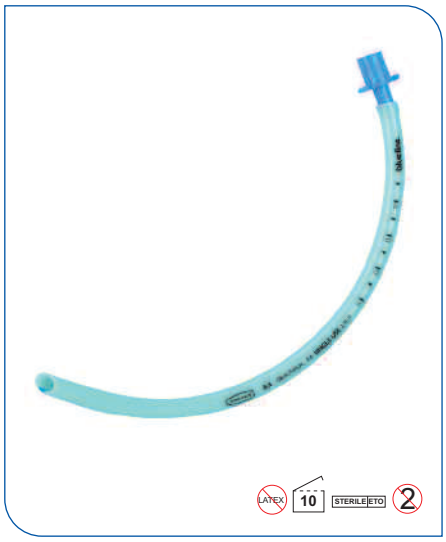
PORTEX™

Uncuffed Tracheal Tubes

IVORY PVC, ORAL/NASAL

ID mm	OD mm	Code
2.5	3.6	100/105/025
3.0	4.4	100/105/030
3.5	5.0	100/105/035
4.0	5.8	100/105/040
4.5	6.6	100/105/045
5.0	7.3	100/105/050
5.5	8.0	100/105/055
6.0	8.8	100/105/060
6.5	9.4	100/105/065
7.0	10.2	100/105/070
7.5	10.9	100/105/075
8.0	11.6	100/105/080
8.5	12.4	100/105/085
9.0	13.1	100/105/090*

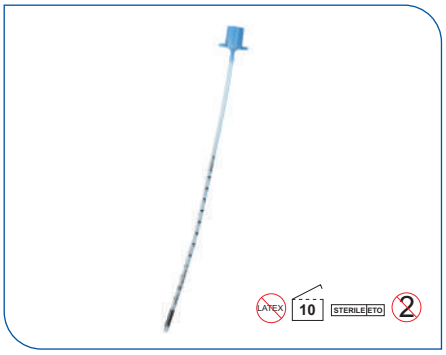
*Please note: This item is made to order only, please contact Customer Services with regard to lead time.



PAEDIATRIC, SILICONISED PVC, ORAL/NASAL CROUP TUBE, EXTRA LONG

ID mm	OD mm	Length mm	Code
2.5	3.5	220	100/112/025*
3.0	4.2	250	100/112/030*
3.5	4.8	280	100/112/035*
4.0	5.5	310	100/112/040*
4.5	6.2	330	100/112/045*
5.0	6.8	330	100/112/050*

*Please note: This item is made to order only, please contact Customer Services with regard to lead time.



Ivory PVC Tracheal Tube

These high quality tubes provide a direct and unimpeded airway for gases to pass to and from the lungs.

These tubes are firm enough for ease of intubation yet soften when in place to conform to the anatomy of the upper respiratory tract.

- Kink-resistant, minimises possibility of tube occlusion
- Ivory PVC minimises the risk of trauma to the nasal passages
- Comprehensive size range 2.5 - 10.0mm to suit all patients from paediatric to adult
- Radio-opaque Blueline® for exact location of tube position
- 15mm connector conforming to ISO5356-1 ensuring full compatibility with circuit connections

Paediatric, Siliconised PVC, Oral/Nasal Croup Tube, Extra long

This extra long paediatric tracheal tube is designed to minimise the problems associated with intubating a patient suffering from croup, upper airway inflammation or epiglottitis.

- Kink resistant, minimises possibility of tube occlusion
- Smooth formed Murphy Eye and tip for atraumatic intubation
- Comprehensive paediatric size range 2.5 - 5.0mm

Uncuffed Tracheal Tubes

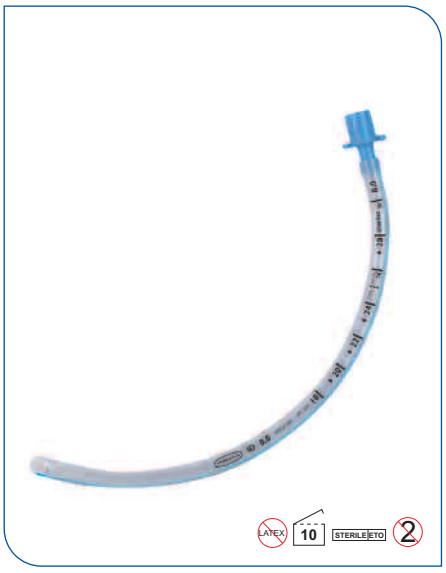
SILICONISED PVC, ORAL/NASAL MURPHY EYE

ID mm	OD mm	Code
2.5	3.4	100/141/025
3.0	4.2	100/141/030
3.5	4.8	100/141/035
4.0	5.5	100/141/040
4.5	6.2	100/141/045
5.0	6.9	100/141/050
5.5	7.6	100/141/055
6.0	8.2	100/141/060
6.5	8.9	100/141/065
7.0	9.6	100/141/070
7.5	10.3	100/141/075
8.0	10.9	100/141/080*
8.5	11.6	100/141/085*
9.0	12.3	100/141/090*
9.5	13.0	100/141/095*

*Please note: This item is made to order only, please contact Customer Services with regard to lead time.

SILICONISED PVC, ORAL/NASAL

ID mm	OD mm	Code
2.0	2.9	100/111/020
2.5	3.4	100/111/025
3.0	4.2	100/111/030
3.5	4.8	100/111/035
4.0	5.4	100/111/040
4.5	6.2	100/111/045
5.0	6.9	100/111/050
5.5	7.6	100/111/055
6.0	8.2	100/111/060
6.5	8.9	100/111/065
7.0	9.6	100/111/070
7.5	10.3	100/111/075
8.0	10.9	100/111/080
8.5	11.6	100/111/085
9.0	12.3	100/111/090



Siliconised PVC Tracheal Tube

Manufactured from implantation tested non toxic Siliconised PVC, helps to protect the delicate mucosal tissue. These tubes have a comprehensive size range 2.0 - 11.0mm to suit all patients from paediatric to adult. Also available with a Murphy Eye from size 2.5mm.

- Provides a direct and unimpeded airway for gases to pass to and from the lungs
- Firm enough for ease of intubation yet softens when in place to conform to the anatomy of the upper respiratory tract
- Manufactured from implantation tested non-toxic siliconised PVC to protect delicate mucosal tissues
- Kink-resistant minimises possibility of tube occlusion
- Radio-opaque Blueline® for exact location of tube position
- 15mm connector conforming to ISO 5356-1 ensuring full compatibility with circuit connections
- Comprehensive size range 2.0 - 11.0mm to suit all patients
- Single use, no risk of cross infection

PORTEX™

Single Use Reinforced Tracheal Tubes

SINGLE USE, PVC, CUFFED TRACHEAL TUBE, MURPHY EYE

ID mm	OD mm	Length mm	Code
5.0	17	259	100/110/050
5.5	17	287	100/110/055
6.0	23	297	100/110/060
6.5	23	307	100/110/065
7.0	30	318	100/110/070
7.5	30	328	100/110/075
8.0	30	338	100/110/080
8.5	30	338	100/110/085
9.0	30	338	100/110/090
9.5	30	338	100/110/095

SINGLE USE, PVC, UNCUFFED TRACHEAL TUBE

ID mm	Length mm	Code
3.0	175	100/113/030
3.5	195	100/113/035
4.0	215	100/113/040
4.5	245	100/113/045
5.0	259	100/113/050

PVC, Single use, reinforced, Oral/Nasal Tracheal Tubes

The Smiths Medical single use reinforced Tracheal tube has been specifically designed to reduce crushing and kinking when the patient head is extended and flexed.

It facilitates the administration of anaesthetic confidently as the airway stays patent. This tracheal tube also boasts all the advantages of a Portex® Tracheal tube and the option of a Profile Soft Seal® Cuff.

- Smoothly finished tube tip
- Atraumatic cuff welds for ease of intubation
- Flexible to conform to patients position
- Single use minimises the risk of cross infection

Masks & Accessories

DISPOSABLE ANAESTHETIC FACE MASK, PREMIUM AIR CUSHION

Description	Hook Ring	Code
Adult	Blue	5045
Small Adult	Yellow	5055
Child	Clear	5048
Toddler	Green	5070
Infant	None	5052
Neonatal	None	5071

PREMIUM PLUS AIR CUSHION WITH INFLATION VALVE

Description	Hook Ring	Code
Adult	Blue	5245
Small Adult	Yellow	5255
Child	Clear	5248
Toddler	Green	5270

ACCESSORIES

Description	Units	Code
Catheter Mount Adaptor Female 15mm	10	100/251/001
Connector - Swivel 15mm reusable	10	100/250/001
Connector Fibreoptic Bronchoscope Swivel 15mm	10	100/257/000
Connector Double Swivel	10	100/255/150
Connector - Tracheal tube set 15mm reusable	10	100/253/000
Adaptor/Connector - Face Mask Co-axial 15mm	10	100/274/000
Y Piece Connector	10	100/276/000
Catheter Mount without double swivel connector	20	100/590/000
Catheter Mount with double swivel connector	10	100/594/000
Flex Tube 6.5"	50	002837
Flex Tube with Gas Sampling Elbow 6.5"	50	002838
Cuff Inflator Pressure Gauge with Connecting Tubes	1	100/568/000
Separate connecting tubes	1	100/569/000

Masks

Smiths Medical offers a comprehensive selection of disposable single use Anaesthesia Face Masks.

- Malleable cone conforms to patient features
- Colour coded hook rings on selected masks
- Available from neonatal to adult sizes
- Crystal clear cone allows the clinician visualisation

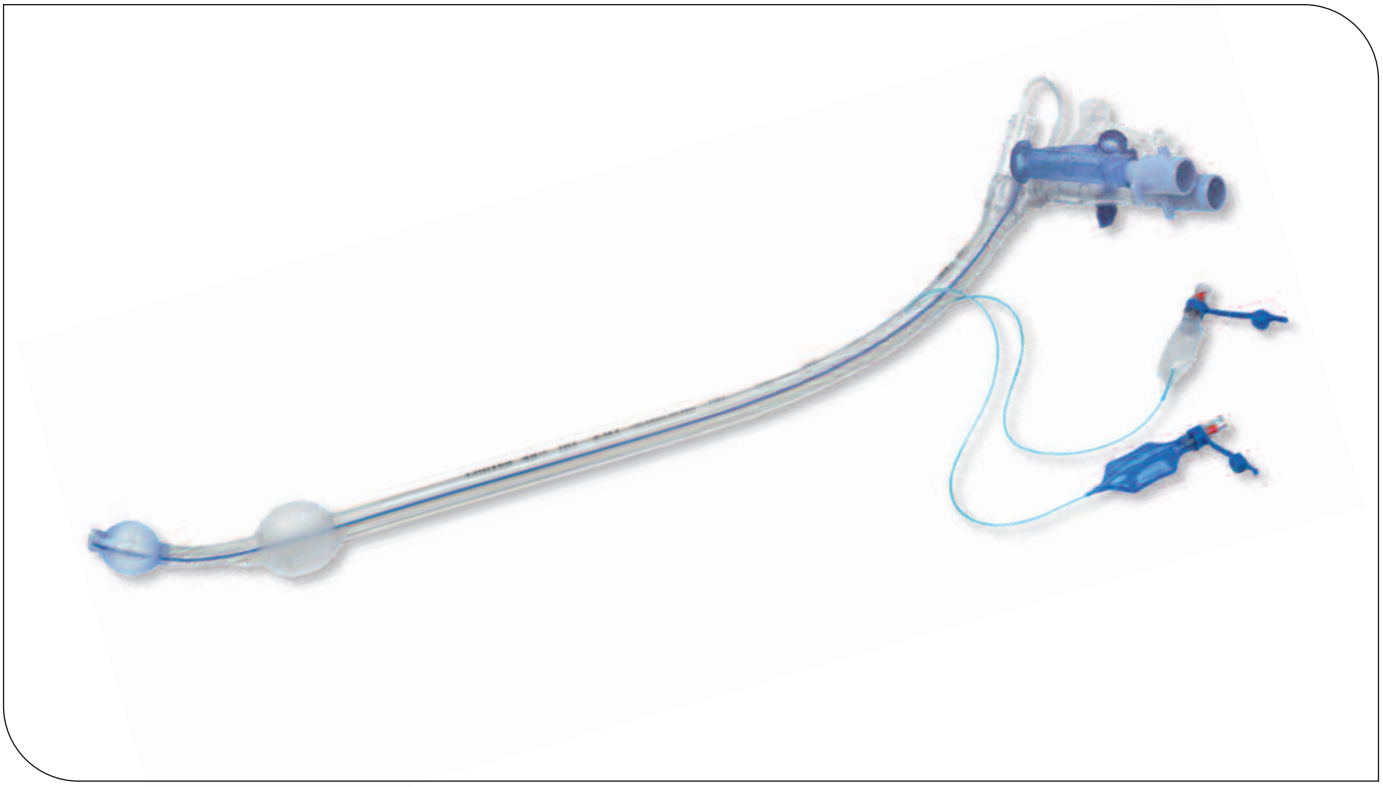
Airway Accessories & Connectors

Smiths Medical manufactures a variety of high quality accessories to support effective Airway Management.

- Catheter Mounts are lightweight by design
- The versatile Cuff inflation gauge combines the advantages of controlled cuff inflation with precise pressure monitoring
- The Y piece connector is a modified Ayres T piece that has a flow tube at an acute angle to reduce bulk

PORTEX™

Endobronchial Tubes



Endobronchial Tube Size	Tracheal Cuff Resting Diameter	Bronchial Cuff Resting Diameter	Maximum Bronchoscope Size	Suction Catheter Size	Maximum Equivalent Airway	Units p/case	Code
28 Fr Left	23mm	12mm	3.2mm	8 Fr 2.6mm	4.6mm	1	198/28L
28 Fr Right	23mm	13mm	3.2mm	8 Fr 2.6mm	4.6mm	1	197/28R
32 Fr Left	24mm	13mm	3.8mm	10 Fr 3.3mm	5.4mm	1	198/32L
32 Fr Right	24mm	13mm	3.8mm	10 Fr 3.3mm	5.4mm	1	197/32R
35 Fr Left	26mm	18mm	4.1mm	10 Fr 3.3mm	6.0mm	1	198/35L
35 Fr Right	26mm	21mm	4.1mm	10 Fr 3.3mm	6.0mm	1	197/35R
37 Fr Left	28mm	18mm	4.4mm	10 Fr 3.3mm	6.3mm	1	198/37L
37 Fr Right	28mm	21mm	4.4mm	10 Fr 3.3mm	6.3mm	1	197/37R
39 Fr Left	29mm	23mm	4.7mm	10 Fr 3.3mm	6.6mm	1	198/39L
39 Fr Right	29mm	21mm	4.7mm	10 Fr 3.3mm	6.6mm	1	197/39R
41 Fr Left	31mm	23mm	5.0mm	12 Fr 4.0mm	7.0mm	1	198/41L
41 Fr Right	31mm	21mm	5.0mm	12 Fr 4.0mm	7.0mm	1	197/41R

Portex® Blueline® Endobronchial Tube

Blueline® Endobronchial Tubes are specifically designed to enhance user technique and patient safety. The unique right angle circuit take-off minimises torque on the tube and directs the circuit up and over the patients head.

- The thermosensitive clear PVC tube softens at body temperature, ensuring maximum anatomical conformity and minimising risk of trauma to the tracheal mucosa
- The Carlens-style wye adaptor allows selective lung ventilation, differential lung ventilation and CPAP
- Colour-coded, labelled extension tubes and pilot balloons differentiate bronchial and tracheal airways
- Pilot balloons indicate cuff inflation status
- The Soft-Seal® high volume/low pressure cuff system minimises risk of airway trauma
- Four separately packaged Maxi-Flow® suction catheters are included
- Pre-assembly of right angle clamping tubes and single axis swivel minimise the torque and direct the circuit away from the operating field
- The tube cuff aids in verification of placement while the larger lumen allows use of larger fibreoptic bronchoscopes and suction catheters (see reference chart)

CATALOGUE NUMBERS, BAR CODES AND BAR CODE NUMBERS

100/585/000

5 019315 020547

Thermovent HEPA Low Deadspace Heat and Moisture Exchange Filter

Thermovent HEPA is a low deadspace bacterial and viral filter with HME properties offering optimum hydrophobic filtration performance.

100/585/000

Product Benefits

Thermovent HEPA (24hrs) Performance Parameter

- **Moisture Loss**
  (= 37.6mg H_2O/L – **Moisture Output**)

	Moisture Loss	Moisture Output
Vt 250ml 20 b.min^{-1}	12 mg H_2O/L	25.6 mg H_2O/L
Vt 300ml 17.5 b.min^{-1}		
Vt 500ml 15 b.min^{-1}	19 mg H_2O/L	18.6 mg H_2O/L
Vt 750ml 12 b.min^{-1}	20 mg H_2O/L	17.6 mg H_2O/L
Vt 1000ml 10 b.min^{-1}	22 mg H_2O/L	15.6 mg H_2O/L

- **Resistance to Flow**

	(6hrs)	(24hrs)
30 L min	1.4 hPa (cm H_2O)	1.5 hPa (cm H_2O)
60 L min	3.0 hPa (cm H_2O)	3.3 hPa (cm H_2O)
90 L min	4.7 hPa (cm H_2O)	5.0 hPa (cm H_2O)

- **Bacterial Filtration Efficiency**
  (Challenge of 10^7 *Bacillus subtilis* var niger 0.7 to 1.0µm) MPV = Microbial Penetration Value
  Bacterial filtration:
  fresh 99.99999% MPV ≤ 1 preconditioned 99.99999% MPV ≤ 10
- **Viral Filtration Efficiency**
  (Challenge of 10^7 MS-2 Coliphage 0.023µm) MPV = Microbial Penetration Value
  Viral filtration:
  fresh 99.999% MPV ≤ 1 preconditioned 99.999% MPV ≤ 10
- **Deadspace (compressible volume)** – 45 ml
- **Recommended Tidal Volume Range** – 150 ml – 1200 ml
- **Gas Leakage @ 70 hPa (cm H_2O)** – <1 ml.min^{-1}
- **Dry Weight** – 29g
- **Compliance** – Rigid filter housing
- **Maximum Recommended Period of Use** – 24 hrs.

Sizes & Technical Data

Order Code	
100/585/000	Sterile, single use

Supplied individually packed in cartons of 50 units

PORTEX