Certificat de Înregistrare

Intertek

Se certifică prin prezenta că sistemul de management al calității al

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Republica Cehă

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, asamblarea, fabricarea, ambalarea și furnizarea de:

Dispozitive și Accesorii pentru Obstetrică și Ginecologie,
Dispozitive și Accesorii Intervenție Imagistică,
Dispozitive de Management al Oxigenului și Umidității,
Dispozitive și Accesorii de Management al Durerii,
Dispozitive și Accesorii Invazive de Monitorizare a Tensiunii Pacientului,
Dispozitive Traheotomie,
Dispozitive de Unică Folosință pentru Injecții,
Dispozitive Catetere Aspirare,
Sisteme de Dispozitive de Intubare.

Certificat Număr: **1201-04 B**
Data Inițială a Certificării: **10 Ianuarie, 2014**
Data Efectivă a Certificatului: **22 Mai 2017**
Data Expirării Certificatului: **28 Februarie 2019**

UKAS MANUFACTURING 9751/05

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
Acest Certificat este proprietatea AMTAC Certification Services Ltd

****

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
TRADUCĂTOR AUTORIZAT

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

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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

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

Subantreprenor	Servicii furnizate
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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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.

****

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

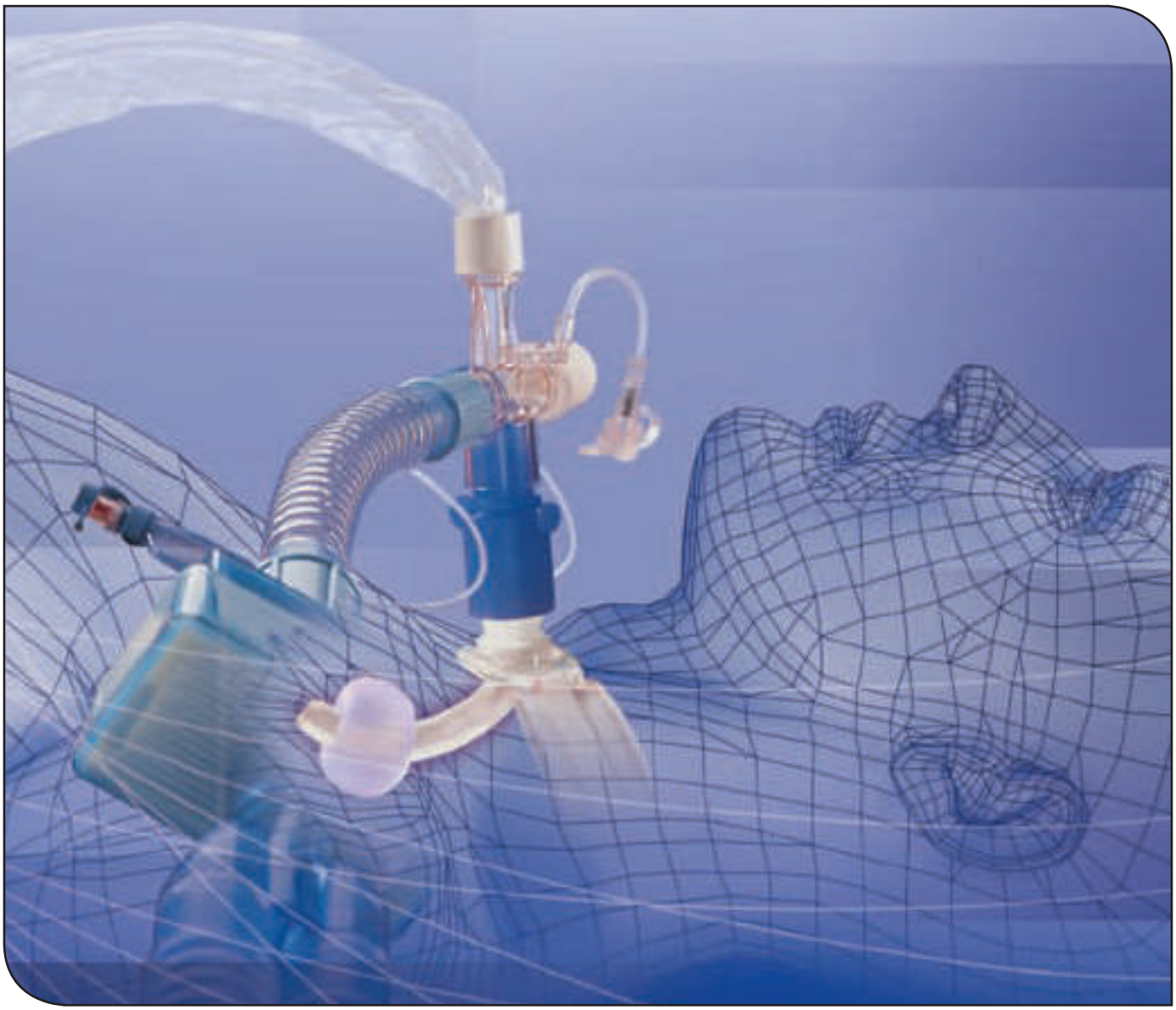
UKAS MANAGEMENT SYSTEMS
061

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

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Ex. Nr. 2769
TRADUCĂTOR AUTORIZAT
Franceză

smiths medical
bringing technology to life

Tracheostomy Supplement
Helping you sustain life



AIRWAY MANAGEMENT

PORTEX™

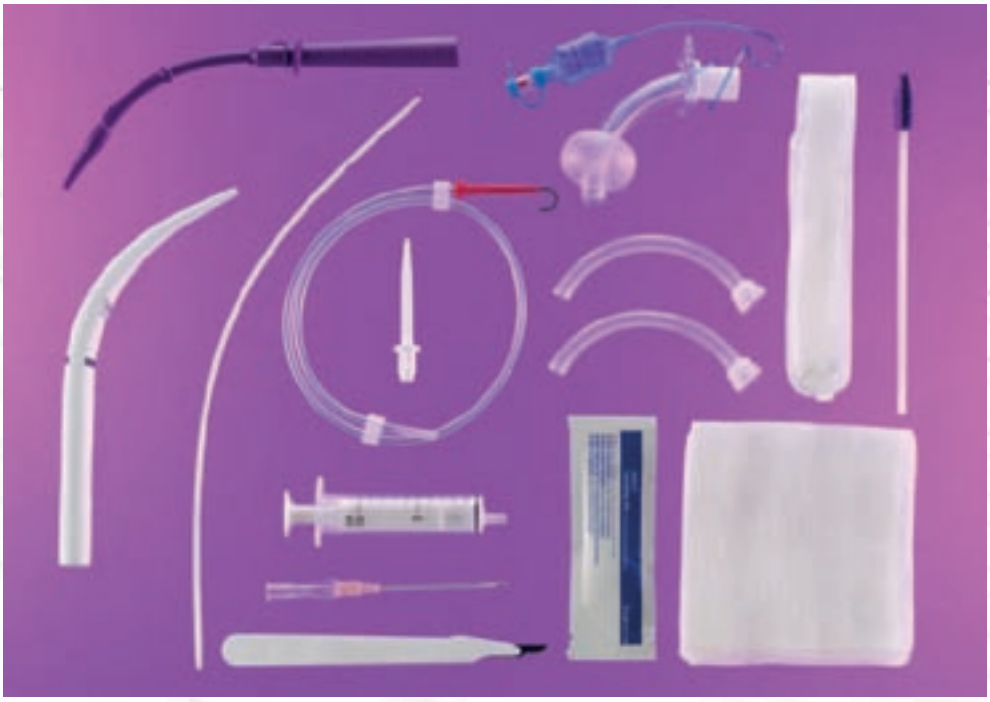
New ULTRAperc kits for percutaneous dilational tracheostomy

ULTRAperc provides the clinician with a range of totally integrated procedural kits for percutaneous dilational tracheostomy for use in Intensive Care or theatre.

Only ULTRAperc kits include every component required from initial incision to final tube insertion using a purpose designed introducer. Also, because ULTRAperc kits are available with Blue Line Ultra, by using ULTRAperc you will gain all the added benefits of this innovative and popular range of tracheostomy tubes.

ULTRAperc is produced with the meticulous attention to detail and quality you expect from Smiths Medical, and offers the clinician:

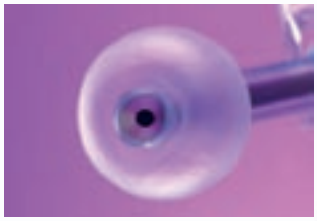
- Totally integrated components, with unique introducer
- The advantages of Blue Line Ultra
- A wide choice of kits to meet individual requirements
- A convenient package including everything required for the procedure
- Ergonomic design for ease of use
- Cost-effective kits



ULTRAperc

PERCUTANEOUS TRACHEOSTOMY KITS

A close fit - the ULTRAperc introducer is tailor made for Blue Line Ultra tracheostomy tubes. The tapered tube tip fits the introducer to minimise trauma on insertion.



A convenient package - Only Smiths Medical ULTRAperc PDT kits can offer the option of the unique introducer and Blue Line Ultra tracheostomy tube all in one kit, avoiding the compromise of mis-matched components.

An ergonomic design - the handle of the ULTRAperc single stage dilator has a chevron-style design, giving a good grip when use of lubricant jelly makes for slippery handling.

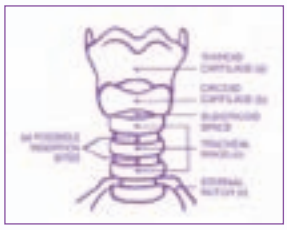
The benefits of Blue Line Ultra - ULTRAperc PDT kits with Blue Line Ultra include all the advantages of this tube range: Soft-Seal cuff, flexible flange, tapered tip, thermo-sensitive PVC material for patient comfort and is suitably radio-opaque for x-ray visualisation.

Also available - Smiths Medical has produced supporting educational material for users of the ULTRAperc kit. The 'How To Guide: Percutaneous Tracheostomy' is produced in association with Care of the Critically Ill. The educational video demonstrates the technique for inserting Blue Line Ultra tubes using the ULTRAperc system.

ULTRAperc kits for percutaneous dilational tracheostomy

Using Ultraperc single dilation technique

1. With the patient in the supine position, hyperextend the neck using a suitable support.



2. Locate and mark the anatomical landmarks. Prepare patient for surgery. Suction pharynx and (if present) re-establish airway with the tracheal tube cuff above the vocal cords to avoid the risk of damaging the tube. If appropriate, inject the site with local anaesthetic.

3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.

4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.

5. Ease the guidewire introducer out from its sheath and straighten the 'J' tip, leaving a sufficient length of exposed guidewire (2-3cm) to enable its dispensing with the forefinger and thumb.

6. Using the introducer, feed the guidewire into the trachea.

7. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.

8. Pass the long guiding catheter over the guidewire into the trachea in the direction of the arrow marked on the catheter (safety stop end first) until the safety stop on the guiding catheter is located at the skin. Align the proximal end of the guiding catheter with the proximal band mark on the guidewire to determine the depth of insertion.

9. Immediately prior to insertion, immerse the distal end of the "single stage" dilator in sterile water or saline to activate the lubricious coating on the dilator. Pass the dilator over the guiding catheter until it reaches the "safety stop". In this position, the proximal mark on the guiding catheter will just be visible at the handle end of the dilator.

10. Whilst stabilising the guidewire and guiding catheter to ensure they remain stable and in position in the trachea, insert and partially remove the dilator several times in order to slightly over-dilate the trachea to a size appropriate for the tracheostomy tube to be inserted. The dilator is marked, for guidance, with 38FR and maximum insertion depth.

11. Insert the lubricated tracheostomy tube located on its lubricated introducer over the guiding catheter through the stoma with a slight twisting motion.

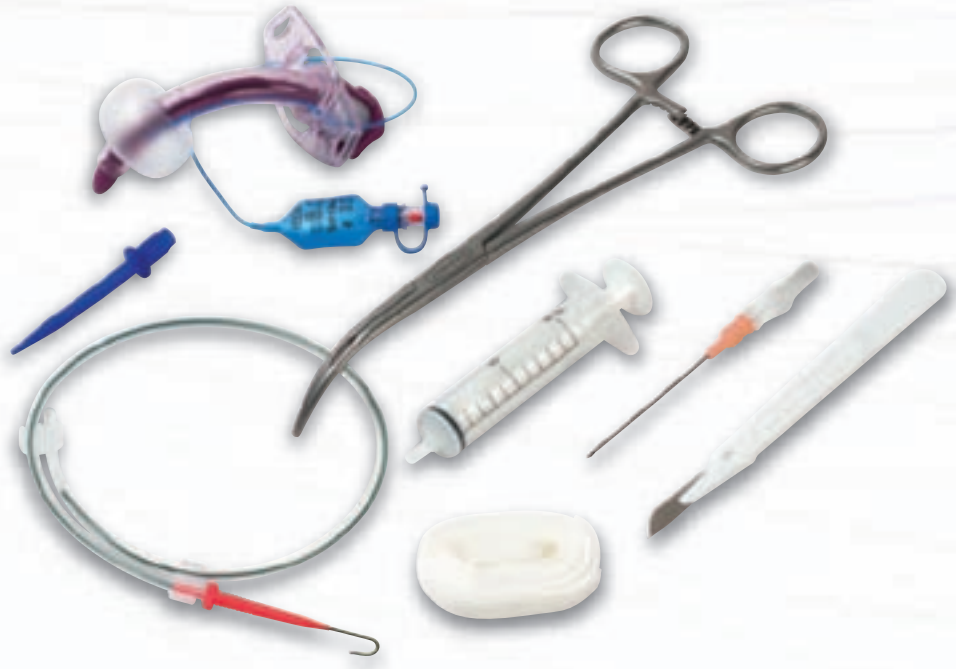
Griggs dilating forceps kits for percutaneous tracheostomy

Based on the widely accepted Seldinger guidewire technique, these kits incorporate the unique and patented Griggs guidewire dilating forceps.

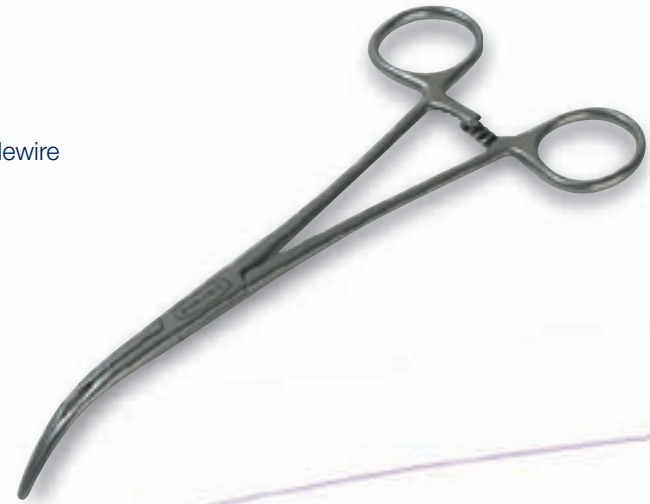
The design of the Griggs forceps permits:

- Single step dilation
  - No need for repeated insertions
  - Minimises tracheal trauma
  - One instrument for a wide range of adult sizes
- Retention of guidewire in situ throughout procedure
  - Maintains accuracy and safety

Smiths Medical kits for Griggs technique percutaneous tracheostomy provide the option for immediate minimally invasive and minimally disruptive treatment, at the bedside or in theatre, which has been shown to have lower complications and morbidity rates versus the traditional surgical technique. [1,2]



References:
1: Griggs WM, Myburgh JA, Worthley LIG. A prospective comparison of a percutaneous tracheostomy technique with standard surgical tracheostomy. Int Care Med 1991; **17**: 261-263.
2: Leinhardt DJ, Mughal M, Bowles B, Glew R, Kishen R et al. Br J Surg 1992; **79**: 255-258.



Only Smiths Medical kits include the unique, patented Griggs guidewire dilating forceps:

- Lock over guidewire for easy, atraumatic insertion
- Allow single step dilation
- Minimise tracheal trauma
- Re-usable to ensure cost-effectiveness

Smiths Medical kits provide what you need:

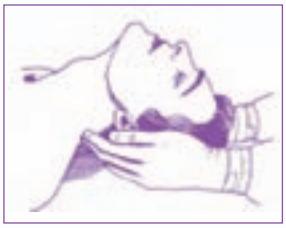
- Full procedure pack (excluding drapes) - avoids delay and inconvenience
- Kits available with or without guidewire dilating forceps - for flexible economy
- Include a Smiths Medical tracheostomy tube with unique guidewire obturator - to ensure convenience and compatibility
- Choice of three tracheostomy tube sizes - to suit a wide range of patients

Kits are also available with the Adjustable Flange Tracheostomy Tube:

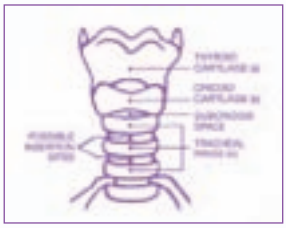
- Moveable flange to facilitate stoma hygiene
- Suitable for patients with deep-set tracheas
- Tapered tube tip and tapered obturator which clips onto bonded connector aid tube insertion
- Siliconised PVC eases passage of suction catheter

Kits for Griggs technique percutaneous tracheostomy

Using the Griggs technique



1. With the patient in the supine position, hyperextend the neck using a suitable support.



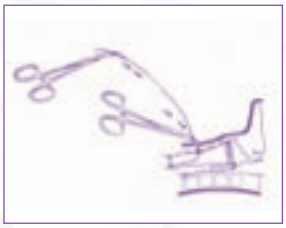
2. Locate and mark the anatomical landmarks. Prepare patient for surgery. Suction pharynx and (if present) re-establish airway with the tracheal tube cuff above the vocal cords to avoid the risk of damaging the tube. If appropriate, inject the site with local anaesthetic.

3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.

4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.

5. Using the introducer, feed the guidewire into the trachea.

6. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.



7. Thread the guidewire through the clamped Guidewire Dilating Forceps and advance the forceps until the anterior tracheal wall is reached. Dilate the pre tracheal tissues by opening the forceps and remove the forceps in the open position.

8. Re-thread the forceps as described and now advance through the tracheal wall. Raise forceps handles into the vertical position so that the forceps jaws further penetrate the tracheal wall and lie longitudinally in the trachea. Dilate the trachea by opening forceps. Remove forceps in the open position.

9. Thread the guidewire through the obturator of the tracheostomy tube and advance both into the trachea. Remove obturator and guidewire.

Ordering information

Smiths Medical **Blue Line Ultra** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/541/070
Kit with 8mm I.D. tracheostomy tube	100/541/080
Kit with 9mm I.D. tracheostomy tube	100/541/090

Smiths Medical **Blue Line Ultra Suctionaid** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/891/070
Kit with 8mm I.D. tracheostomy tube	100/891/080
Kit with 9mm I.D. tracheostomy tube	100/891/090

Smiths Medical **Blue Line Ultra** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/543/070
Kit with 8mm I.D. tracheostomy tube	100/543/080
Kit with 9mm I.D. tracheostomy tube	100/543/090

Smiths Medical **Blue Line Ultra Suctionaid** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/893/070
Kit with 8mm I.D. tracheostomy tube	100/893/080
Kit with 9mm I.D. tracheostomy tube	100/893/090


100/541


100/543


100/891


100/893

Smiths Medical **Blue Line** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/540/070
Kit with 8mm I.D. tracheostomy tube	100/540/080
Kit with 9mm I.D. tracheostomy tube	100/540/090

Smiths Medical **Adjustable Flange** Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/545/070
Kit with 8mm I.D. tracheostomy tube	100/545/080
Kit with 9mm I.D. tracheostomy tube	100/545/090

Smiths Medical **Blue Line** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

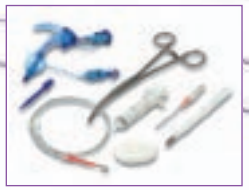
Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/542/070
Kit with 8mm I.D. tracheostomy tube	100/542/080
Kit with 9mm I.D. tracheostomy tube	100/542/090

Smiths Medical **Adjustable Flange** Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/546/070
Kit with 8mm I.D. tracheostomy tube	100/546/080
Kit with 9mm I.D. tracheostomy tube	100/546/090


100/540


100/542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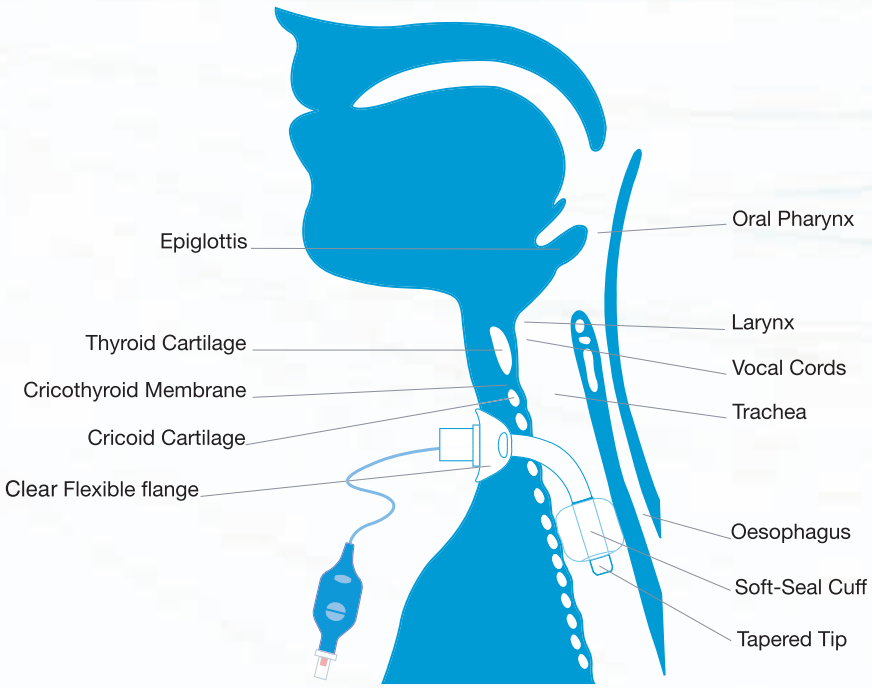
Blue Line Ultra with inner cannula

The benefits of the Blue Line Ultra inner cannula system

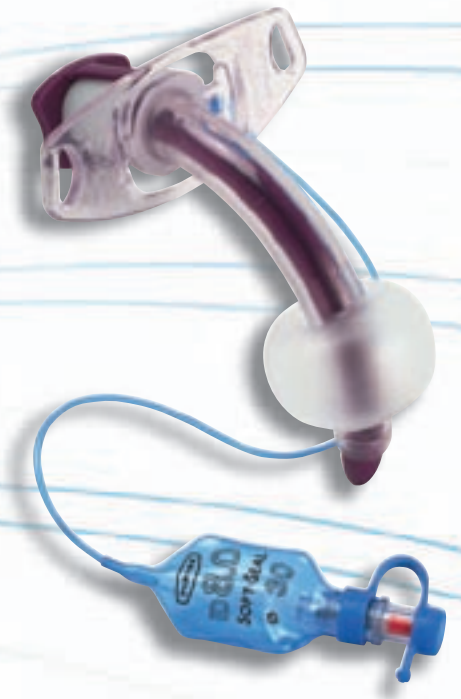
- Inner cannula designed to be robust and easy to use. Clicks into place to confirm correct insertion. Can be used for up to 30 days
- Ring-pull design aids smooth insertion and removal from tube, minimising patient trauma
- Size of inner cannula indicated to avoid errors in use
- 15mm ISO termination is permanent part of the tube, patient can be ventilated with or without inner cannula in place
- A cleaning brush is supplied for cleaning inner cannula. Brush features soft nylon filaments and smooth brush tip
- Fenestrated inner cannula is coloured red for ease of identification of use
- Multiple fenestrations match those of tracheostomy tube and minimise risk of blockages
- Provided with two reusable inner cannulae and tube holder to secure tube



Blue Line Ultra tracheostomy tubes

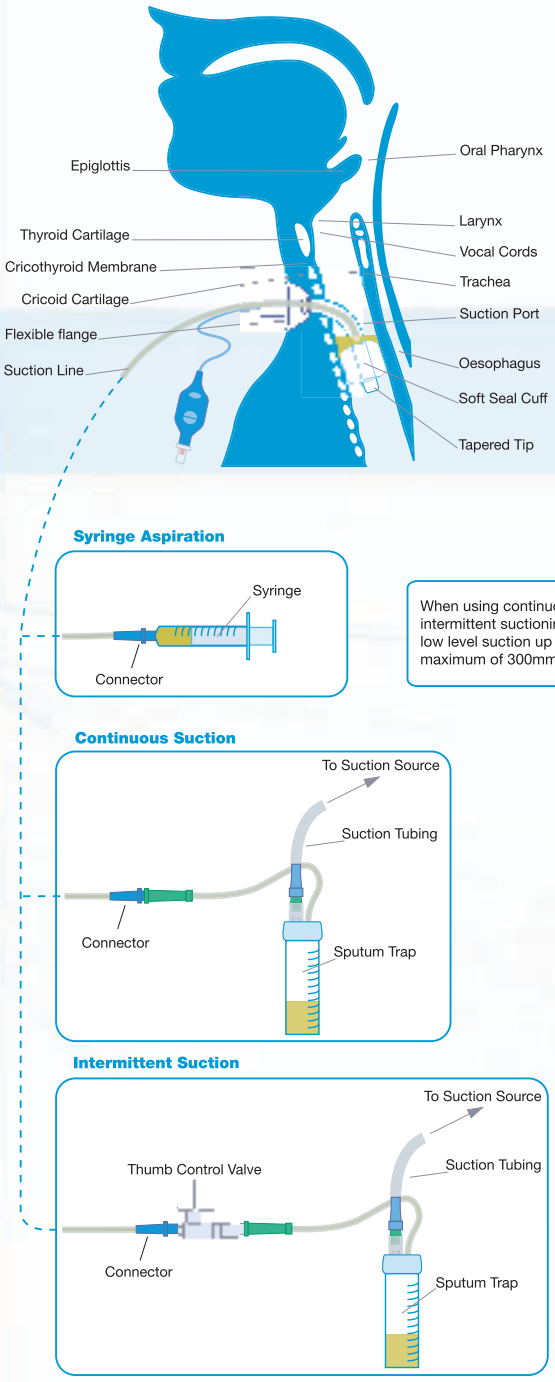
When caring for a patient with a tracheostomy, you need to choose the tracheostomy tube that best suits the specific clinical need. The Blue Line Ultra range has many benefits:

- Comprehensive range - available with or without inner cannula, cuffed or uncuffed, rigid or thermosensitive, fenestrated or unfenestrated
- Thermosensitive PVC tubes provides sufficient rigidity for initial insertion, and then softens at body temperature to accommodate individual patient anatomy
- Soft-Seal cuff - low pressure, high volume cuff for minimal trauma whilst providing an effective seal. When deflated, cuff relaxes smoothly to tube minimising discomfort on insertion and removal. Velvet soft material with larger cuff resting diameter
- Clear markings on pilot balloon provide relevant information
- Flange is soft for maximum patient comfort, and clear to ensure aesthetic acceptability
- Tube material is suitably radio-opaque to enable confirmation of tube position
- Multiple fenestrations to minimise risk of occlusions
- Obturator provides rigidity for tube insertion. Rounded obturator tip for insertion with minimal trauma
- Special clip design minimises obturator tip movement during tube insertion



New Blue Line Ultra Suctionaid

A new addition to the Blue Line Ultra range, the Blue Line Ultra Suction Aid is ideal for improving patient well-being by maintaining a clean, hygienic and unobstructed airway and having the ability to remove secretions from above the cuff.



Reducing the potential risk of infection

Accumulation and stasis of contaminated mucus and subglottic secretions above the cuff of tracheostomy tubes can be uncomfortable for patients and provides an ideal growth medium for pathogens. The integral suction lumen of Blue Line Ultra Suctionaid allows removal of these pooled secretions.

Reducing the risk of aspiration

However good the cuff, microaspiration of contaminated material can potentially lead to pulmonary infection. Maintaining tracheostomy hygiene and regular removal of secretions with Blue Line Ultra Suctionaid can help reduce this aspiration.

Blue Line tracheostomy tubes

The comprehensive range of Blue Line tracheostomy tubes meets the varying needs of different departments and different patients.

In Surgery the primary requirement is for ventilation, which needs an atraumatic tube with a good cuff seal against air and liquid. These needs are met by Blue Line cuffed, thermosensitive tubes.

In Intensive Care the patient also needs to be weaned off ventilation, and to restart vocalisation. Tubes for this setting, as well as being atraumatic with a good cuff seal against air and liquid, need to permit airflow to the larynx. Blue Line cuffed, thermosensitive, fenestrated tubes fulfil this requirement.

On the Ward spontaneous breathing obviates the need for the cuff, while vocalisation demands airflow to the larynx. For these patients Blue Line uncuffed thermosensitive tubes are ideal.

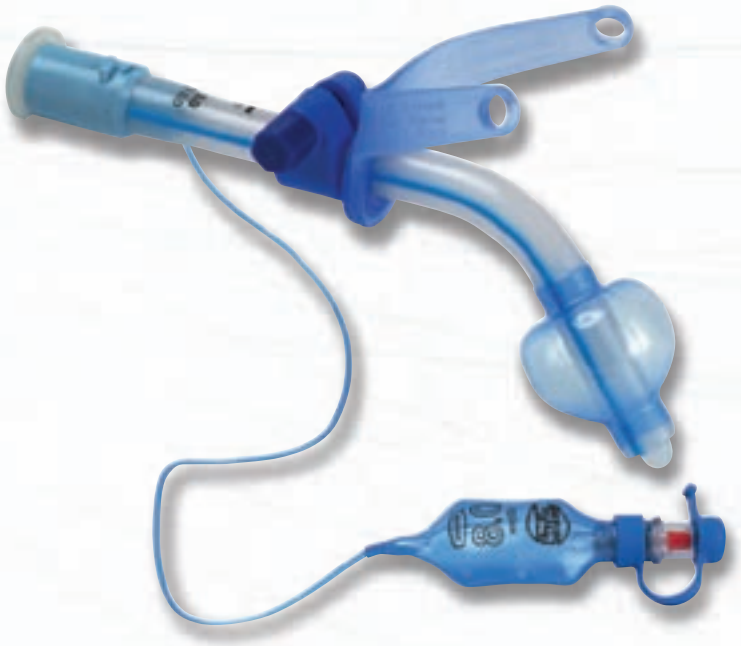
In the Home, patients who still require a tracheostomy although they are breathing spontaneously and vocalising want a tube which is unobtrusive, as well as atraumatic and permitting a good airflow to the larynx. For them the solution is a Blue Line uncuffed, thermosensitive, fenestrated tube with no 15mm connector.

The Blue Line range is also broad and flexible enough to cover the enormous variation in individual patient anatomy by offering customised tubes (see pages 56-62).

Blue Line tracheostomy tubes

Blue Line tubes are designed to meet all your needs.

- Thermosensitive material
  - Initial rigidity for easy intubation
  - Flexibility at body temperature to adapt to the individual patient's anatomy
- Atraumatic design
  - Anatomical tube shape
  - Smooth contours for maximum comfort
  - Non-toxic siliconised PVC tube
  - Low pressure, high volume Profile cuff
- Large choice of tubes
  - Cuffed or uncuffed, fenestrated or unfenestrated, with or without 15mm connector
  - Specialised products for specific needs



Blue Line tracheostomy tubes

Ordering information

Cuffed tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Profile cuff tube	6-10	10	100/518/060 - 100/518/100
Double cuff tube	7-10	10	100/512/070 - 100/512/100
Vocalaid tube	6-10	10	100/517/060 - 100/517/100

Uncuffed tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Uncuffed tube	3-10	10	100/506/030 - 100/506/100
Uncuffed single fenestrated tube	3-10	10	100/536/030 - 100/536/100
Uncuffed double fenestrated tube	6-10	10	100/537/060 - 100/537/100

Uncuffed tubes without 15mm connector

Product	Sizes (I.D.mm)	Pack size	Product Codes
Uncuffed tube	3-10	10	100/505/030 - 100/505/100
Uncuffed fenestrated tube	3-10	10	100/535/030 - 100/535/100

Adjustable flange tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Profile cuff tube	6-10	2	100/523/060 - 100/523/100
Uncuffed tube	6-10	2	100/526/060 - 100/526/100

The last 3 digits indicate the correct tube size e.g. for a size 8.0mm I.D. tube, the product code is 100/518/080

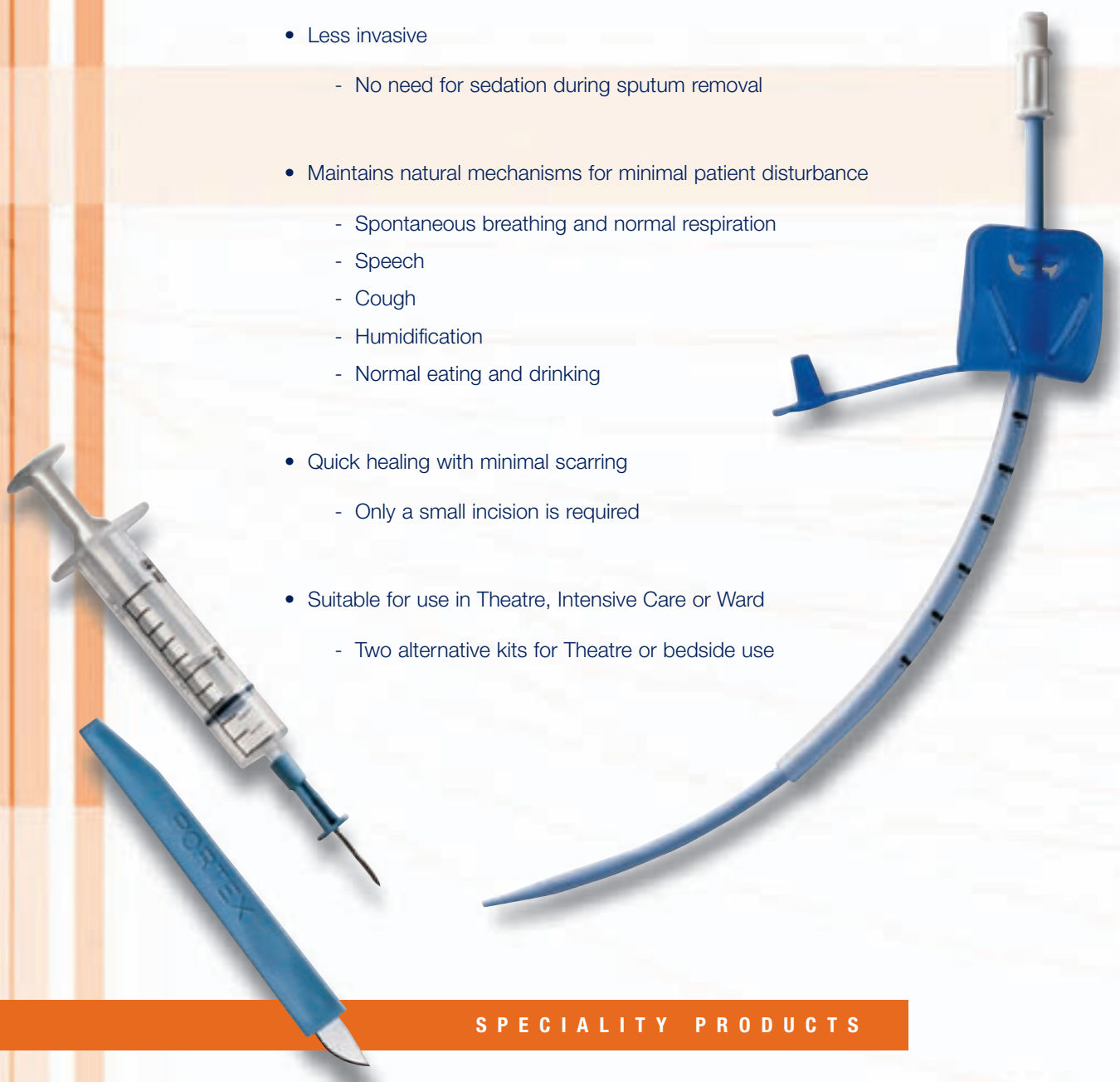
No inner cannulae are available for these products.

100/505 products are available single packed. To order replace '0' with '1' - e.g. 100/505/130.
Code for size 10mm tube as single item is 100/505/110.

Mini-Trach II minitracheotomy kits

After surgery, infection or injury, sputum retention can be a real problem which, if not effectively treated can lead to significant morbidity and even death. When there is the risk that natural sputum removal by coughing, with or without physiotherapy, will not be adequate, prophylactic minitracheotomy can prevent the problem arising and offers many advantages over conventional techniques for managing sputum retention: [4,5,6,7]

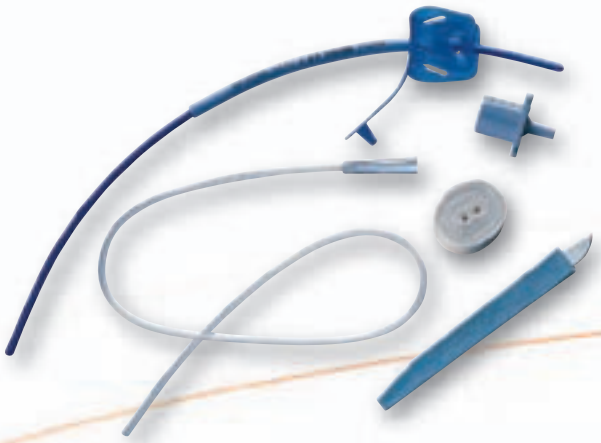
- Constant tracheal access
  - No need for tracheal intubation or tracheostomy
- Less invasive
  - No need for sedation during sputum removal
- Maintains natural mechanisms for minimal patient disturbance
  - Spontaneous breathing and normal respiration
  - Speech
  - Cough
  - Humidification
  - Normal eating and drinking
- Quick healing with minimal scarring
  - Only a small incision is required
- Suitable for use in Theatre, Intensive Care or Ward
  - Two alternative kits for Theatre or bedside use



4: HR Matthews, RB Hopkinson "Treatment of sputum retention by mini tracheostomy" Brit J Surg 1984: 71: 147-150
5: Mini tracheostomy and the control of sputum, HR Matthews. Surgeon Annual 1998. Appleton & Lange, USA P39-59
6: P Bonde, I Papachristos, A McCraith, B Kelly, C Wilson, JA McGuigon, K McManus, "Sputum Retention after Lung Operation: Randomised trial shows superiority of prophylachc minitracheostomy in high-risk patients" Ann Thoracic Surg 2002; 74: 196-203
7: P Bonde, K McManus, M McMnespie, J MuGuigon "Lung Surgery: identifing the subgroup at risk for sputum retention" European Journal of Cardio-Thoracic Surgery 22(2002) 18-22

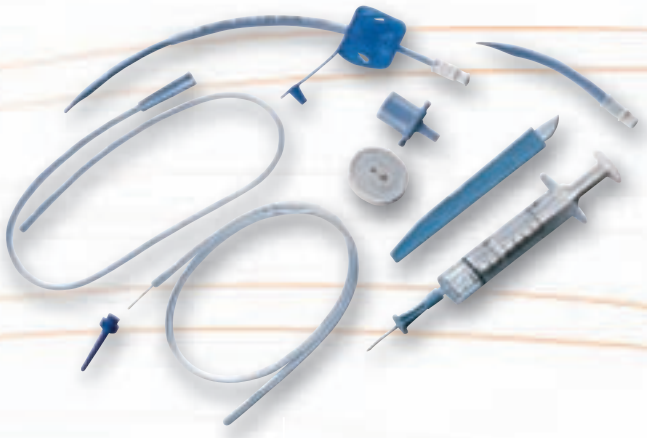
Mini-Trach II kit for surgical insertion in Theatre

- Guarded scalpel allows the correct incision to be made without risk of damage to the posterior wall of the trachea
- Introducer guides the cannula into the trachea
- 4.0mm ID soft PVC cannula provides access to the trachea both as an airway and for suctioning
- 15mm connector allows standard connection to breathing systems. 10F low friction suction catheter allows immediate initial suctioning following cannulation



Mini-Trach II Seldinger kit for therapeutic insertion in Theatre, Intensive Care or Ward

- Guarded scalpel to make initial midline skin incision
- 16G bevelled needle allows simple puncture of the cricothyroid membrane
- Aspirating syringe allows confirmation of correct needle placement
- Flexible tipped guidewire helps introduction of dilator without trauma to posterior tracheal wall
- Curved dilator expands the opening to permit smooth insertion of the Mini-Trach cannula
- Introducer guides the cannula into the trachea
- 4.0mm ID soft PVC cannula provides access to the trachea both as an airway and for suctioning
- 15mm connector allows standard connection to breathing systems
- 10F low friction suction catheter allows immediate initial suctioning following cannulation



Mini-Trach II minitracheotomy kits

Using the Mini-Trach II Seldinger kit

1. The patient is positioned supine with head, neck and chin fully extended. The operator stands above the patient's head facing the patient's feet.

2. The skin is cleansed and the position of the cricothyroid membrane located by palpation and marked.

3. A midline vertical 1cm skin incision is made using the guarded scalpel.

4. The 16G bevelled needle is fitted to the syringe. With the trachea immobilised the bevelled needle is inserted vertically (with the opening of the needle facing caudally) through the cricothyroid membrane. Correct placement is confirmed by aspiration of air.

5. The syringe is removed carefully, keeping the needle in position. The flexible tip of the guidewire is inserted through the bevelled needle into the trachea.

6. The bevelled needle is removed carefully while holding the guidewire to ensure that the guidewire is not moved out of position.

7. The curved dilator is fed onto the guidewire and passed through the cricothyroid membrane.

8. The dilator is removed carefully while holding the guidewire to ensure that the guidewire is not moved out of position. The curved introducer with the premounted Mini-Trach cannula is then fed onto the guidewire and introduced into the trachea with firm pressure.

9. The introducer and guidewire are removed holding the cannula flange in place against the skin.

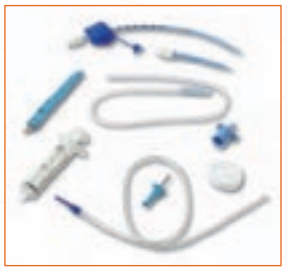
10. The cannula is fixed in place with neck tapes.

11. The suction catheter is passed immediately to remove any existing blood and secretions.

Ordering information

Mini-Trach II

Description	Pack Size	Product Code
Seldinger kit	5	100/461/000
Non-Seldinger kit	10	100/462/000



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