

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

See appendix for additional sites and additional site scopes

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

EN ISO 13485:2016

The management system is applicable to:

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

The Servicing of active medical devices.

Certificate Number:

119-04 C

Initial Certification Date:

08 June 2004

Date of Certification Decision:

25 June 2018

Issuing Date:

25 June 2018

Valid Until:

24 June 2021



061

Calin Moldovean

President, Business Assurance

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

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

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





CERTIFICAT DE ÎNREGISTRARE

Se certifică prin prezenta că sistemul de management al:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn,
Germania

Pentru locații și domenii suplimentare, vedeți anexa

a fost înregistrată de către Intertek deoarece se
conformează cerințelor:

EN ISO 13485:2016

Sistemul de management este aplicabil pentru:

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

Service-ul dispozitivelor medicale active.

Certificat Număr:

119-04 C

Data Certificării Inițiale:

08 Iunie 2004

Data Deciziei Certificării:

25 Iunie 2018

Data Emiterii:

25 Iunie 2018

Valabil Până la:

24 Iunie 2021



Semnătura - indescifrabilă

Calin Moldovean

Președinte, Business Assurance

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

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

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

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



Traducător autorizat
Nr. 2769/2015



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

EC Certificate - Full Quality Assurance System

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

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

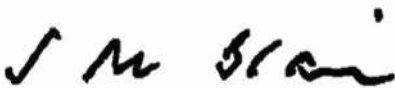
Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

In respect of:

See certificate scope page.

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

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2017-06-28**

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

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

Certificate No: CE 661325

Certificate Scope:

The design, development and manufacture of sterile:

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

The design, development and manufacture of non-sterile:

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

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

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

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EC Certificate - Full Quality Assurance System

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

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

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

Subcontractor:	Service(s) supplied
Smiths 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

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

Subcontractor:	Service(s) supplied
Smiths Medical Gary 5700 W 23rd Ave Gary Indiana 46406 USA	Manufacture
Smiths Medical International Ltd 52 Grayhill Rd Cumbernauld Glasgow G68 9HQ United Kingdom	Manufacture
Smiths Medical International Nijmegen Bijsterhuizen 22-08 6604 LD Wijchen The Netherlands	Distribution

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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 Somercoates 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

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

Subcontractor:	Service(s) supplied
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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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

Certificat CE - Sistem Integral de Asigurare a Calitatii

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

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

Obiect:

Consultati pagina cu obiectul certificatului.

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

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



Stewart Brain, Sef compartiment conformitate si risc

Dispozitive medicale

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

Data: **2017-06-28**

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

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Pagina 1 din 2

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

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



Certificat nr.: CE 661325

Obiectul certificatului:

Proiectarea, dezvoltarea si fabricatia produselor sterile:

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

Proiectarea, dezvoltarea si fabricatia de produse nesterile:

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



Prima editie: 2017-06-28

Data: 2017-06-28

Data expirarii: 2022-06-27

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Pagina 2 of 2

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

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

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



Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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

Subcontractant:

Servicii prestate

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

Fabricatie

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

Fabricatie

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

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

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

Subcontractant:

Servicii prestate

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

Fabricatie

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

Furnizor crucial

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

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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

Subcontractant:

Servicii prestate

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

Fabricatie

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

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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

Subcontractant:

Servicii prestate

Smiths 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

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

Subcontractant:**Servicii prestate**

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

Fabricatie

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

Distributie

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

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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

Subcontractant:

Servicii prestate

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

Fabricatie

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

Fabricatie

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

Distributie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

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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 prestatii aferente produsului certificat prin:

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

Subcontractant:**Servicii prestate**

Sterigenics US, LLC
344 Bonnie Circle
Corona
California
92880
USA

Sterilizare cu raze gamma

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

Sterilizare cu raze gamma

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

Sterilizare ETO

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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

Subcontractant:

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

Servicii prestate

Sterilizare ETO

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

Fabricatie

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

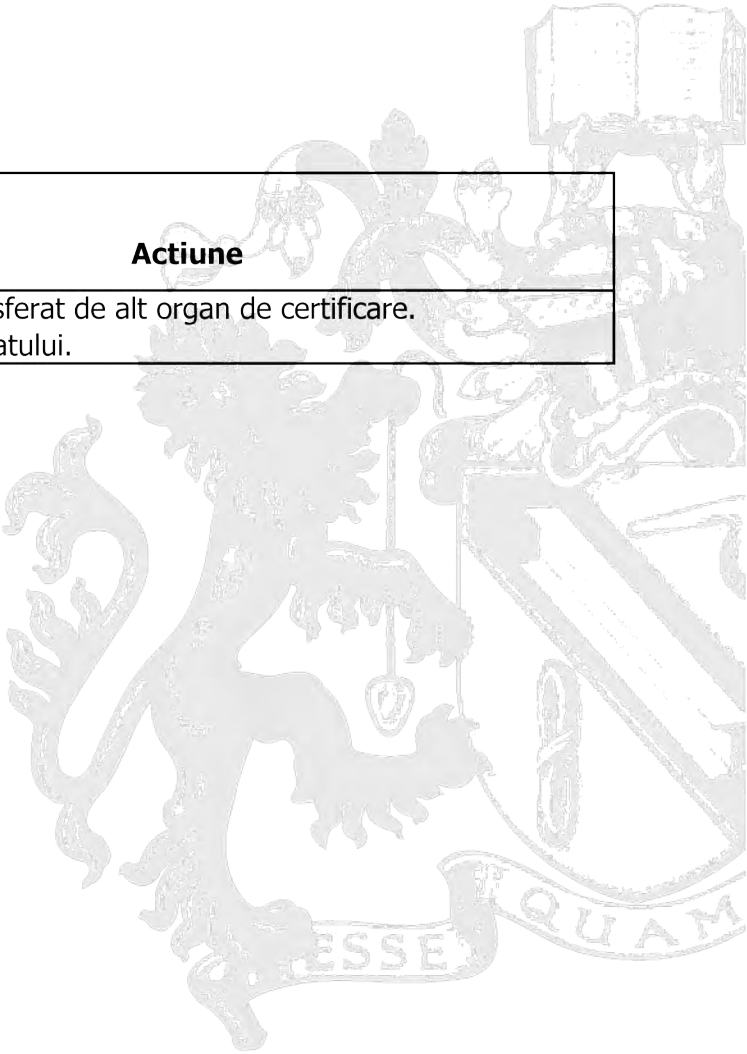
Furnizor crucial

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

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

Data	Numar de referinta	Actiune
Curenta	8603100 8603169	Prima editie. Transferat de alt organ de certificare. Reinnoirea certificatului.



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

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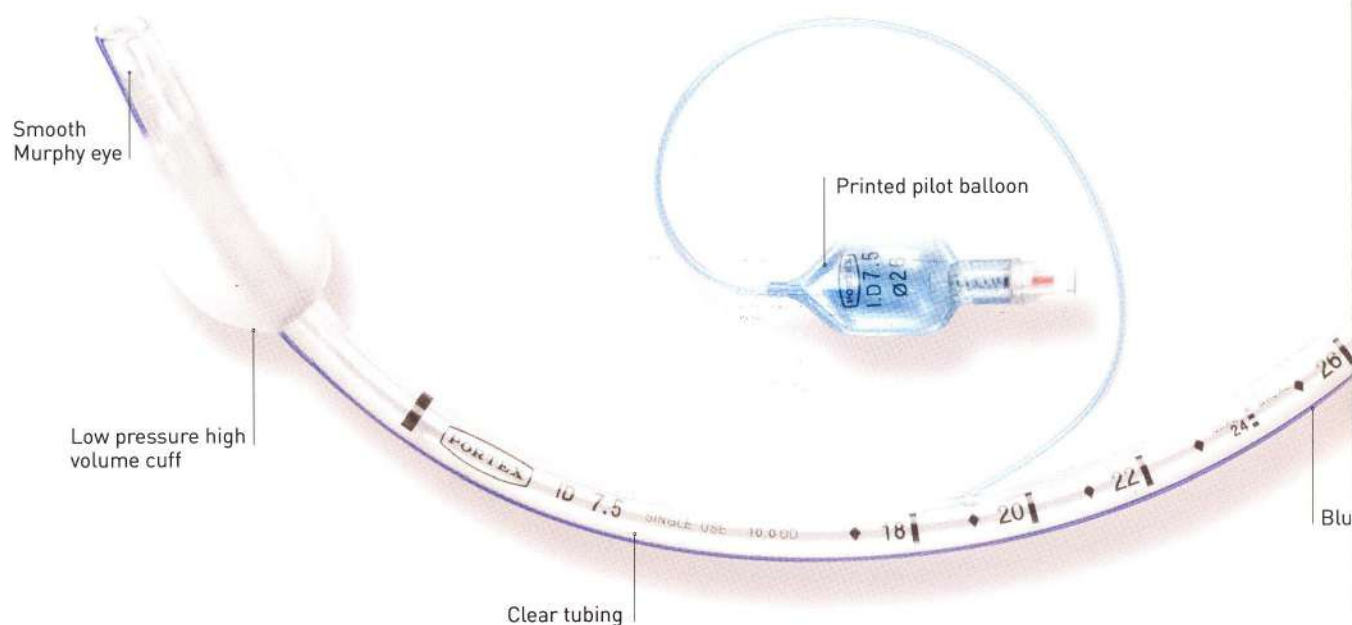
Portex® Choice Tracheal Tubes for the Operating Room
Affordable quality - SMILE!



AIRWAY MANAGEMENT

PORTEX

TM



The New Portex® Tracheal Tube

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

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

Affordable quality

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

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

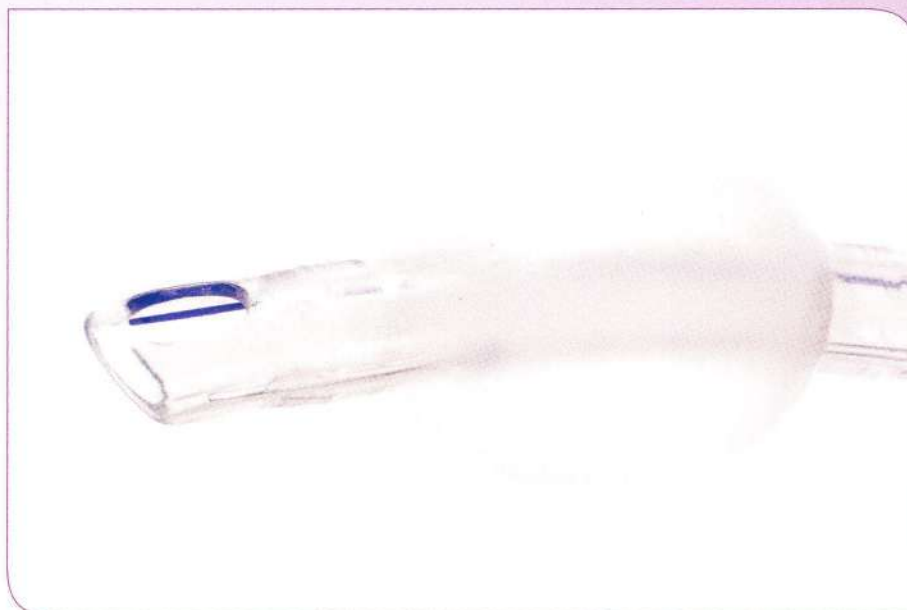
Low pressure seal

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

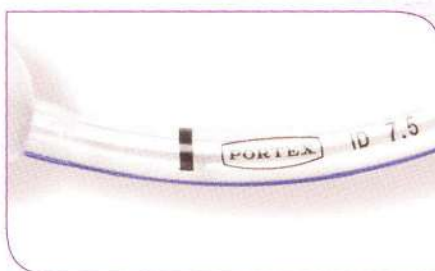
The large cuff resting diameter relieves the pressure on the tracheal wall ensuring patient safety and comfort.

Blue 15mm connector

Radio-opaque line



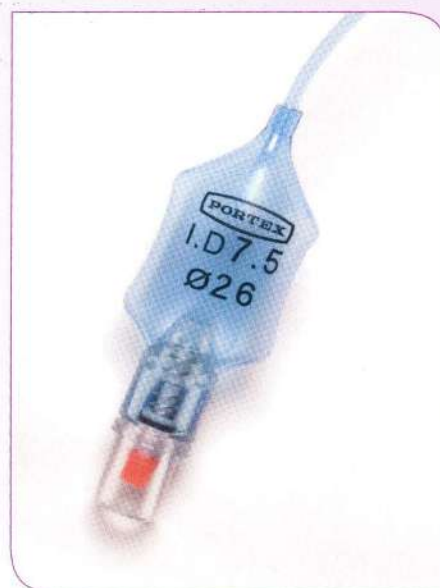
Low pressure high volume cuff



Intubation depth marker



Smooth Murphy eye



Printed pilot balloon

Superior smooth finish

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

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

Easily identifiable

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

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

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

Fully informed

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

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

Portex® Choice Tracheal Tube

For short-term intubation within the operating room

ORDERING INFORMATION

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

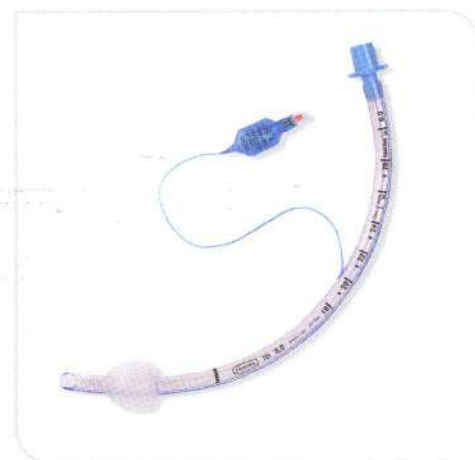


Portex® Soft Seal® Tracheal Tube

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

ORDERING INFORMATION

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



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

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

ORDERING INFORMATION

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



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