

EC Certificate - Full Quality Assurance System

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

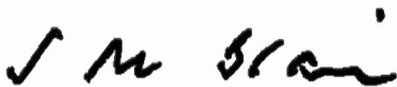
No. **CE 661325**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

In respect of:

See certificate scope page.

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

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2017-06-28**

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

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Page 1 of 2

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

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

Certificate No: CE 661325

Certificate Scope:

The design, development and manufacture of sterile:

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

The design, development and manufacture of non-sterile:

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

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

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Page 2 of 2

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

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

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

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EC Certificate - Full Quality Assurance System

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

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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

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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 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

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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 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

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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
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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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.

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

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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

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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 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

Lista subcontractantilor majori

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

Subcontractant:**Servicii prestate**

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

Fabricatie

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

Distributie

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

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

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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

Subcontractant:**Servicii prestate**

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

Ambalare

Sterigenics Belgium
(Petit-Rechain) SA
Zoning Industriel de Petit-Rechain
Avenue Andre Ernst 21
B-4800 Verviers
Belgium

Sterilizare ETO

Sterigenics UK Limited
Cotes Park Estate
Somercotes
Alfreton
DE55 4NJ
Marea Britanie

Sterilizare ETO

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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

Lista subcontractantilor majori

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:

Servicii prestate

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

Sterilizare ETO

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

Fabricatie

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

Furnizor crucial

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

Certificat nr.: **CE 661325**
 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.

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



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

Traducător autorizat
 Nr. 2769/2015

EC Design-Examination Certificate

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

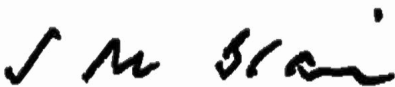
No. **CE 661326**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

In respect of:

Cardiothoracic Catheters.

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

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2017-06-28**

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

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

EC Design-Examination Certificate

Supplementary Information to CE 661326

Issued To:

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

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

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

Date: **2017-06-28**

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

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EC Design-Examination Certificate

Supplementary Information to CE 661326

Issued To:

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

Certificate History

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

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

Date: **2017-06-28**

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

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Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

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**

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

Pagina 1 din 3

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 de examinare a proiectului

Informatii suplimentare pentru CE 661326

Titular:

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

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

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

Data: **2017-06-28**

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

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Pagina 2 din 3

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului 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 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**

Pagina 3 din 3

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

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

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

Traducător autorizat
 Nr. 2769/2015

EC Certificate - Production Quality Assurance

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

No.**CE 661328**

Issued To:

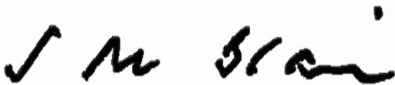
**Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom**

In respect of:

See certificate scope page.

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

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-06-28**Date: **2017-06-28**Expiry Date: **2022-06-27****...making excellence a habit.™**

Page 1 of 2

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

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

Certificate No: CE 661328

Certificate Scope:

The manufacture and final inspection of sterile:

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

The manufacture and final inspection of non-sterile:

Resuscitation Devices, Tracheostomy Tubes, Intubation Systems

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

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

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Page 2 of 2

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

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

EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

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

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

Subcontractor:	Service(s) supplied
Brightwake Limited 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 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 - 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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Page 1 of 1

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

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



By Royal Charter

Traducere din limba engleză

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

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

Cu privire la:
Vedeți domeniul de certificare pe cealaltă pagină.

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

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

Semnătura – indescifrabilă
Stewart Brain, Director Conformitate și Risc
Dispozitive Medicale

Prima emiteră: **28-06-2017** Data: **28-06-2017** Data expirării: **27-06-2022**
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Pagina 1 din 2

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

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

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



bsi.



Certificat Nr.: CE 661328

Domeniu Certificat:

Fabricarea și inspecția finală a următoarelor produse sterile:

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

Fabricarea și inspecția finală a următoarelor produse non-sterile:

Dispozitive de Resuscitare, Tuburi Traheostomie, Sisteme de Intubare.

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

Prima emiterere: **28-06-2017** Data: **28-06-2017**

Data expirării: **27-06-2022**

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Pagina 2 din 2

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

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

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





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

Lista Principalilor Subantreprenori

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

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

Subantreprenor	Servicii furnizate
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

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Pagina 1 din 9

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





By Royal Charter

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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Pagina 2 din 9

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





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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

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Pagina 3 din 9

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





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

Lista Principalilor Subantreprenori

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

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

Subantreprenor

Servicii furnizate

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

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

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

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Pagina 4 din 9

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





By Royal Charter

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 Fabricare
Road, Dublin, Ohio 43016
SUA

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

Smiths Medical Czech Republic a.s. Fabricare
Olomoucka 306, 753 01 Hranice
Republica Cehă

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Pagina 5 din 9

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





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

Lista Principalilor Subantreprenori

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

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

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

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





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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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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.





By Royal Charter

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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
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Sterilization Services of Tennessee, Inc., 2396 Florida Street, Memphis, Tennessee 38109 SUA	Sterilizare ETO
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Pagina 8 din 9

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Lista Principalilor Subantreprenori

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

Subantreprenor

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

Servicii furnizate

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

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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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Pagina 1 din 1

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

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

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

Traducător autorizat
Nr. 2769/2015



Difficult Airways & Intubation completing the picture



AIRWAY MANAGEMENT

Portex® Soft Seal® Laryngeal Mask Range

ORDERING INFORMATION

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



Portex® Soft Seal® Laryngeal Mask range

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

- The Portex® Soft Seal® Laryngeal Mask features the exclusive Soft Seal® Cuff which is less permeable to nitrous oxide¹ than that of reusable masks, reducing increase in pressure and minimising potential trauma.

- The cuff, combined with the higher atrium, helps to provide an improved seal.
- Single Use.
- Better infection control.
- Research has shown that even thoroughly cleaned reusable airway devices still contain residual protein deposits, which have the potential for cross-patient contamination.
- Ease of Access.
- Higher atrium, negating the use of epiglottis bars.
- The Portex® ---Soft Seal® Laryngeal Mask is designed to avoid the risk of blockage without the need for obstructive

- epiglottis bars, allowing easy access for flexible fibre optic devices and fibre optic guided placement of tracheal tubes.
- The Portex® Soft Seal® Laryngeal Mask has been approved in studies for use in pre-hospital airway management.
- Available in paediatric sizes 1, 1.5, 2 and 2.5.

References

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

Introducers, Stylets & Guides

PORTEX® SINGLE USE BOUGIE

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



PORTEX® VENN REUSABLE BOUGIE

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



PORTEX® ET TUBE STYLET

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



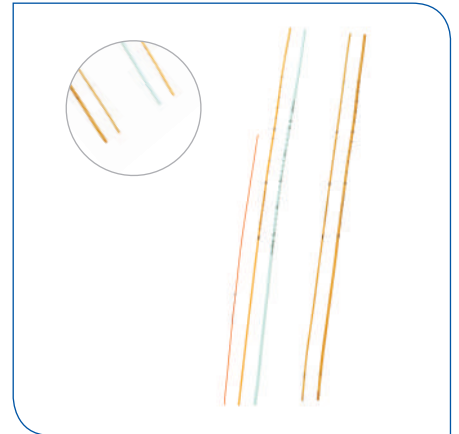
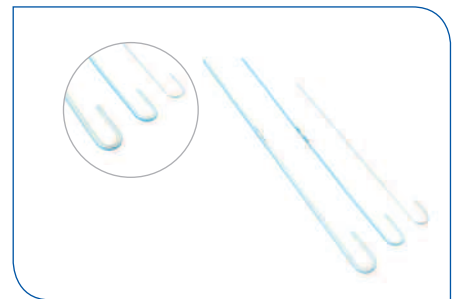
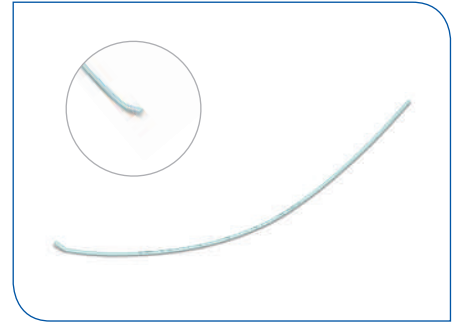
PORTEX® SINGLE USE EXCHANGE GUIDES

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



PORTEX® VENN REUSABLE EXCHANGE GUIDES

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



Bougies

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

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

Stylets

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

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

Guides

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

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

ET Tube Material



Your choice of material

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

- Clear PVC can identify correct intubation through 'misting'
- Siliconised PVC can assist in suctioning in an ICU
- Ivory is soft yet kink resistant for maxilla - facial and nasal intubations

- Polyurethane has no memory so is perfect for uncuffed nasal intubation
- Silicone reinforced for adverse airways
- Single Use PVC reinforced for cervical spinal to reduce the risk of cross infection

Soft Seal® Cuff

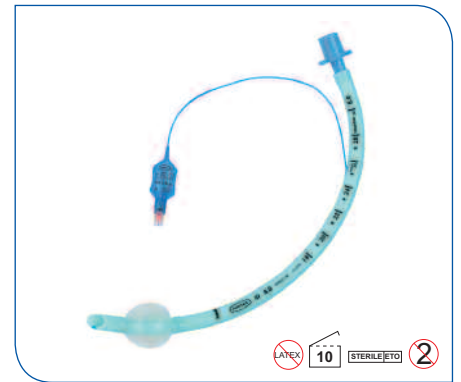
The profile Soft Seal® cuff is made from velvet soft PVC material, giving minimal risk of trauma. Through combining the benefits of the profile cuff design with a larger cuff resting diameter, it ensures an effective seal even when selecting smaller bore tracheal tubes.

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

Tracheal Tubes with Profile Soft Seal® Cuff

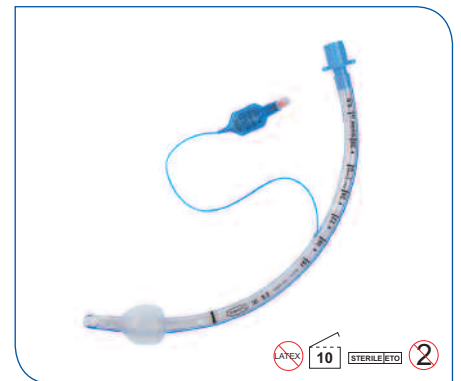
IVORY PVC, NASAL

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



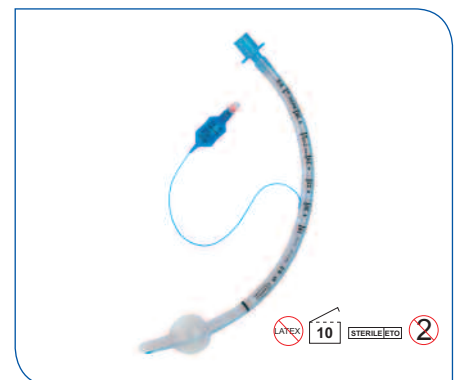
CLEAR PVC, ORAL/NASAL, MURPHY EYE

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



SILICONISED PVC, ORAL/NASAL

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



Tracheal Tubes with Profile Soft Seal® Cuff

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

- Minimal contact with the sensitive tracheal mucosa
- Large cuff diameter ensures effective seal
- Reduces movement relative to trachea during ventilation

- When deflated, cuff conforms closely to tube to minimise the risk of trauma during intubation and extubation
- Low pressure - responds rapidly to varying pressures during the respiratory cycle, securing sealing
- Reduces the risk of trauma during intubation and extubation

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

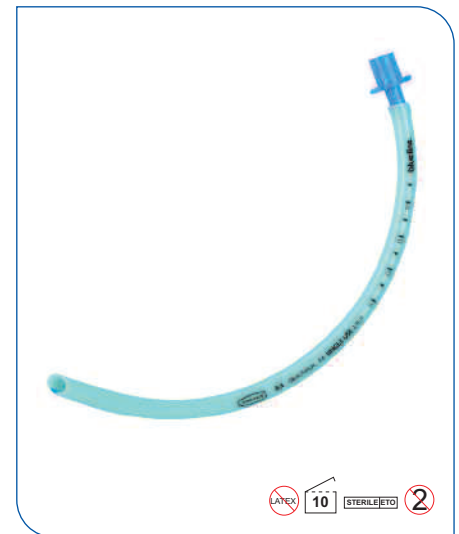
- One way valve for efficient and easy inflation and deflation of cuff
- Large pilot balloon clearly shows when cuff is inflated
- An intubation Depth Marker is located 3cm proximal to the cuff to assist in the accurate placement of the tip within the trachea

Uncuffed Tracheal Tubes

IVORY PVC, ORAL/NASAL

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

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



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

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

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



Ivory PVC Tracheal Tube

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

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

- Kink-resistant, minimises possibility of tube occlusion
- Ivory PVC minimises the risk of trauma to the nasal passages
- Comprehensive size range 2.5 - 10.0mm

to suit all patients from paediatric to adult

- Radio-opaque BlueLine® for exact location of tube position
- 15mm connector conforming to ISO5356-1 ensuring full compatibility with circuit connections

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

This extra long paediatric tracheal tube is designed to minimise the problems associated with intubating a patient

suffering from croup, upper airway inflammation or epiglottitis.

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

Uncuffed Tracheal Tubes

SILICONISED PVC, ORAL/NASAL MURPHY EYE

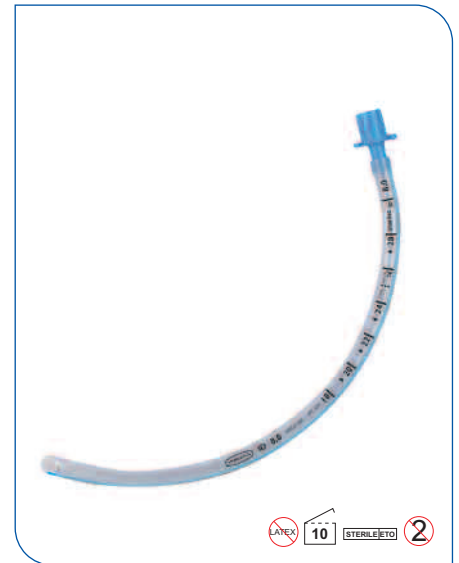
ID mm	OD mm	Code
2.5	3.4	100/141/025
3.0	4.2	100/141/030
3.5	4.8	100/141/035
4.0	5.5	100/141/040
4.5	6.2	100/141/045
5.0	6.9	100/141/050
5.5	7.6	100/141/055
6.0	8.2	100/141/060
6.5	8.9	100/141/065
7.0	9.6	100/141/070
7.5	10.3	100/141/075
8.0	10.9	100/141/080*
8.5	11.6	100/141/085*
9.0	12.3	100/141/090*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

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



SILICONISED PVC, ORAL/NASAL

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



Siliconised PVC Tracheal Tube

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

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

Single Use Reinforced Tracheal Tubes

SINGLE USE, PVC, CUFFED TRACHEAL TUBE, MURPHY EYE

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



SINGLE USE, PVC, UNCUFFED TRACHEAL TUBE

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



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

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

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

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

Masks & Accessories

DISPOSABLE ANAESTHETIC FACE MASK, PREMIUM AIR CUSHION

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

PREMIUM PLUS AIR CUSHION WITH INFLATION VALVE

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



ACCESSORIES

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



Masks

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

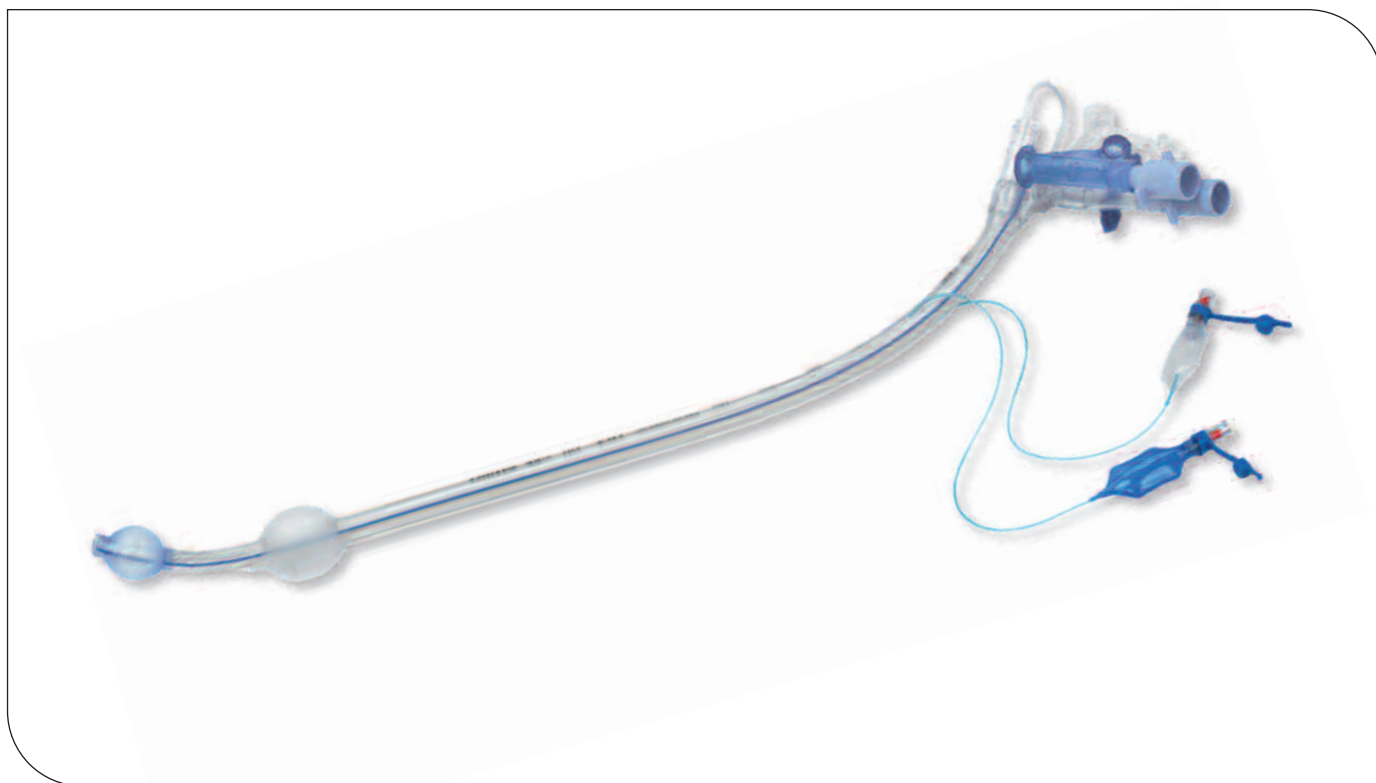
- Malleable cone conforms to patient features
- Colour coded hook rings on selected masks
- Available from neonatal to adult sizes
- Crystal clear cone allows the clinician visualisation

Airway Accessories & Connectors

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

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

Endobronchial Tubes



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

Portex® Blueline® Endobronchial Tube

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

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

100/585/000



Thermovent HEPA Low Deadspace Heat and Moisture Exchange Filter

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

100/585/000

Product Benefits

Thermovent HEPA (24hrs) Performance Parameter

- **Moisture Loss**
(= 37.6mg H₂O/L – Moisture Output)

Vt 250ml 20 b.min ⁻¹ Vt 300ml 17.5 b.min ⁻¹ Vt 500ml 15 b.min ⁻¹ Vt 750ml 12 b.min ⁻¹ Vt 1000ml 10 b.min ⁻¹	Moisture Loss 12 mg H ₂ O/L 19 mg H ₂ O/L 20 mg H ₂ O/L 22 mg H ₂ O/L	Moisture Output 25.6 mg H ₂ O/L 18.6 mg H ₂ O/L 17.6 mg H ₂ O/L 15.6 mg H ₂ O/L
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- **Resistance to Flow**

30 L min 60 L min 90 L min	(6hrs) 1.4 hPa (cm H ₂ O) 3.0 hPa (cm H ₂ O) 4.7 hPa (cm H ₂ O)	(24hrs) 1.5 hPa (cm H ₂ O) 3.3 hPa (cm H ₂ O) 5.0 hPa (cm H ₂ O)
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- **Bacterial Filtration Efficiency**
(Challenge of 10⁷ *Bacillus subtilis* var niger 0.7 to 1.0µm)

Bacterial filtration: fresh 99.99999% MPV ≤ 1	MPV = Microbial Penetration Value preconditioned 99.99999% MPV ≤ 10
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- **Viral Filtration Efficiency**
(Challenge of 10⁷ MS-2 Coliphage 0.023µm)

Viral filtration: fresh 99.999% MPV ≤ 1	MPV = Microbial Penetration Value preconditioned 99.999% MPV ≤ 10
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- **Deadspace (compressible volume) – 45 ml**
- **Recommended Tidal Volume Range – 150 ml – 1200 ml**
- **Gas Leakage @ 70 hPa (cm H₂O) – <1 ml.min⁻¹**
- **Dry Weight – 29g**
- **Compliance – Rigid filter housing**
- **Maximum Recommended Period of Use – 24 hrs.**

Sizes & Technical Data

Order Code

100/585/000

Sterile, single use

Supplied individually packed in cartons of 50 units

PORTEX

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