

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:**

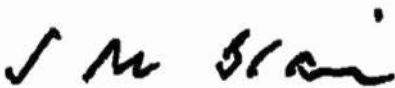
Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

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

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

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

Subcontractor:

Service(s) supplied

Smiths Healthcare Manufacturing
 SA de CV
 Avenida Calidad No.4
 Parque, Industrial Internacional
 Tijuana
 22425
 Mexico

Manufacture

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

Manufacture

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 10 Bowman Dr. Keene New Hampshire 03431 USA	Manufacture
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	Manufacture
Smiths Medical ASD Inc. 201 West Queen St., Southington Connecticut 06489 USA	Manufacture

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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



Certificat nr.: CE 661325

Obiectul certificatului:

Proiectarea, dezvoltarea si fabricatia produselor sterile:

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

Proiectarea, dezvoltarea si fabricatia de produse nesterile:

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



Prima editie: 2017-06-28

Data: 2017-06-28

Data expirarii: 2022-06-27

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Pagina 2 of 2

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

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

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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.
 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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 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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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:

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

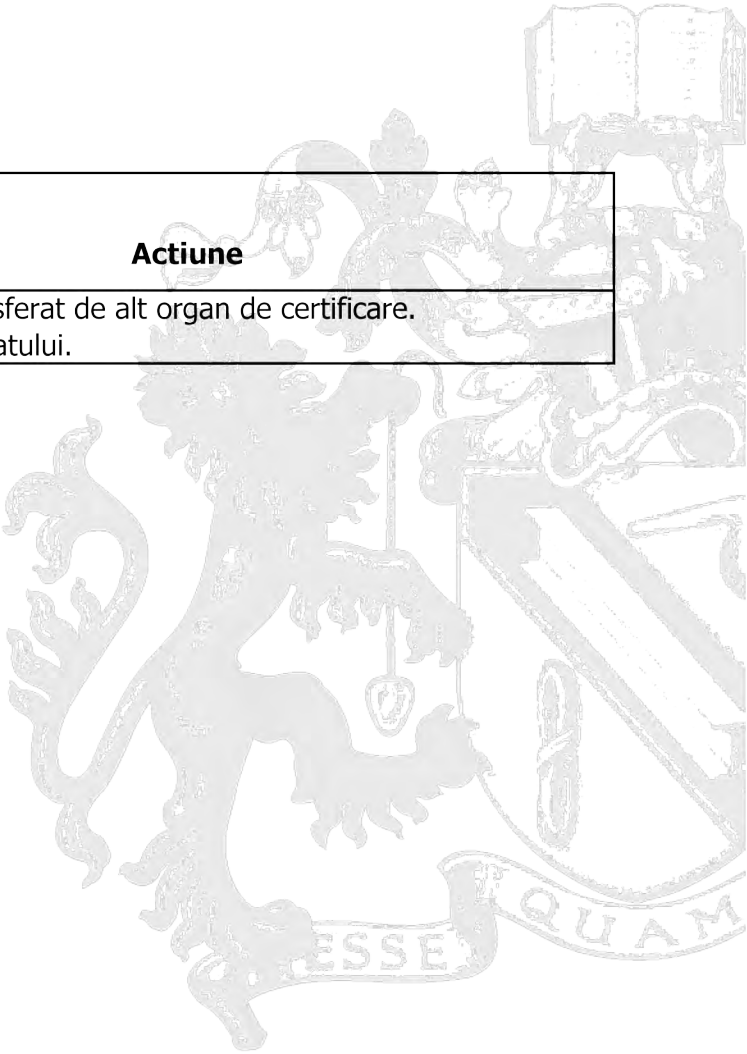
Furnizor crucial

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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.

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



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

Traducător autorizat
Nr. 2769/2015

EC Design-Examination Certificate

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

No.**CE 661326****Issued To:**

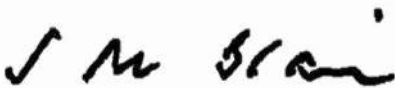
Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

In respect of:

Cardiothoracic Catheters.

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

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2017-06-28**

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

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Page 1 of 3

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

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

EC Design-Examination Certificate

Supplementary Information to CE 661326

Issued To:

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

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

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

Date: **2017-06-28**

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

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Page 2 of 3

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

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

EC Design-Examination Certificate

Supplementary Information to CE 661326

Issued To:

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

Certificate History

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

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

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Page 3 of 3

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

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

Certificat CE de examinare a proiectului

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

Nr. **CE 661326**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Obiectul certificatului:

Catetere cardiotoracice.

BSI a examinat dispozitivele de mai sus conform cerintelor Directivei Consiliului 93/42/CEE, Anexa II, Secțiunea 4. Proiectul indeplinește cerințele Directivei. Pentru lansarea pe piață a acestor produse, este necesar certificatul menționat în Anexa II, excluzând Secțiunea 4.

Pentru și în numele BSI, organ de certificare în acceptiunea sus-menționatei Directive (Organ de certificare cu numărul 0086):



Stewart Brain, Șef compartiment conformitate și risc
Dispozitive medicale

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

Data: **2017-06-28**

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Data expirării: **2022-06-27**

Pagina 1 din 3

Valabilitatea prezentului certificat este condiționată de menținerea sistemului de calitate la cerințele Directivei dovedită de organul de certificare care supraveghează compania. Prezentă aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte on în numele companiei care deține prezentul certificat, cu excepția unui acord contrar, încheiat cu BSI. Prezentul certificat a fost redactat electronic și este condiționat de respectarea caietului de sarcini.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 în 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.

Certificat CE de examinare a proiectului

Informatii suplimentare pentru CE 661326

Titular:

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

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

Prima editie: **2017-06-28**Data: **2017-06-28**Data expirarii: **2022-06-27**
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Pagina 2 din 3

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului de calitate la cerintele Directivei 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

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

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

Subsemnata MUSUROIA MIRELA, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.
Traducător autorizat
Nr. 2769/2015

EC Certificate - Production Quality Assurance

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

No.

CE 661328

Issued To:

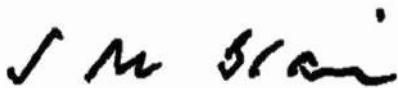
**Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom**

In respect of:

See certificate scope page.

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

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2017-06-28**

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

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Page 1 of 2

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

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

Certificate No: CE 661328

Certificate Scope:

The manufacture and final inspection of sterile:

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

The manufacture and final inspection of non-sterile:

Resuscitation Devices, Tracheostomy Tubes, Intubation Systems

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



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

Date: **2017-06-28**

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

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Page 2 of 2

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

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

EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

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

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

Subcontractor:	Service(s) supplied
Brightwake Limited 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 Somercoates 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 emitere: **28-06-2017** Data: **28-06-2017** Data expirării: **27-06-2022**
.. making excellence a habit.”
Pagina 1 din 2

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

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

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





Certificat Nr.: CE 661328

Domeniu Certificat:

Fabricarea și inspecția finală a următoarelor produse sterile:

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

Fabricarea și inspecția finală a următoarelor produse non-sterile:

Dispozitive de Resuscitare, Tuburi Traheostomie, Sisteme de Intubare.

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

Prima emitere: **28-06-2017**

Data: **28-06-2017**

Data expirării: **27-06-2022**

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Pagina 2 din 2

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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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
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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Hythe
Kent
CT21 6JL
Regatul Unit

Subantreprenor

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

Servicii furnizate

Smiths Healthcare Manufacturing SA de CV Fabricare
Carretera Miguel Aleman km 21.7 Parque
Industrial Monterrey Apodaca
Nuevo Leon 66603
Mexic

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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 SUA	Fabricare
---	-----------

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

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

Subantreprenor

Servicii furnizate

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

Subantreprenor	Servicii furnizate
Smiths Medical Italia Srl, Via della Stazione, Ambalare 2 Latina Scalo, 04100 Italia	

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

Subantreprenor	Servicii furnizate
Sterigenics US, LLC 344 Bonnie Circle, Corona, California 92880 SUA	Sterilizare Gamma

Sterigenics LLC, 1700 College Blvd., West Memphis, Arkansas 72301 SUA	Sterilizare Gamma
--	-------------------

Sterilization Services of Tennessee, Inc., 2396 Florida Street, Memphis, Tennessee 38109 SUA	Sterilizare ETO
---	-----------------

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Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI
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Lista Principalilor Subantreprenori

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

Subantreprenor

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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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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Traducător autorizat
Nr. 2769/2015



Certificate of Registration

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

This is to certify that the quality management system of

SMITHS MEDICAL INTERNATIONAL LIMITED

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

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

EN ISO 13485:2012

The quality management system is applicable to:

Design of:

Breathing Systems, Drainage Devices, Feeding Devices,
Filtration Devices, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology
Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Devices,
Respiratory Mechanics Devices, Resuscitation Devices,
Suction Catheters, Tracheostomy Tubes, Vascular Access Devices, Cardio Thoracic
Catheters and Drapes

Additional Site:

Human Resources and Training, Shipping, Demand Planning, Post Market Surveillance,
Market Intelligence, E-Business, International Customer Services, Business Development,
Registrations, Finance, Wallace Women's Healthcare

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



061

A black ink signature of Brian Johnson, consisting of a stylized 'B' and 'J'.

Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd

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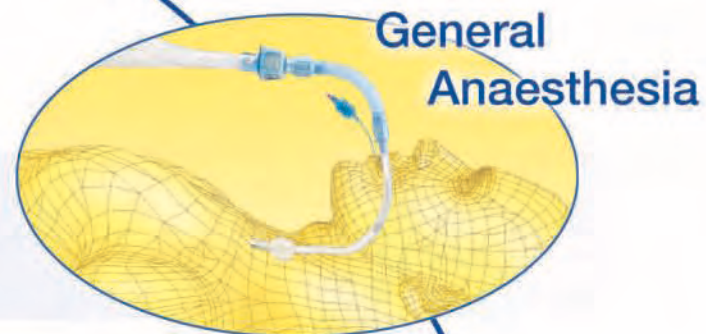
contents

4	Intubation
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40	Anaesthetic Breathing Systems & Accessories
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48	Respiratory Care
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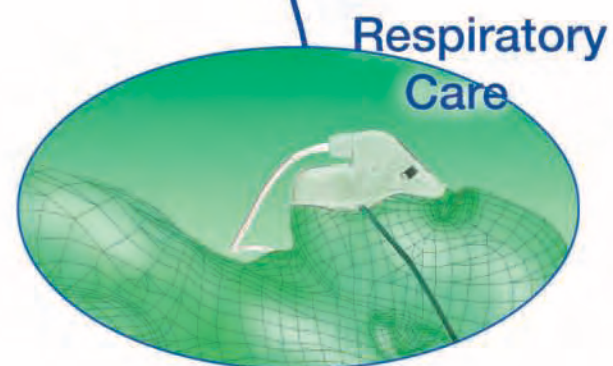
Smiths Medical



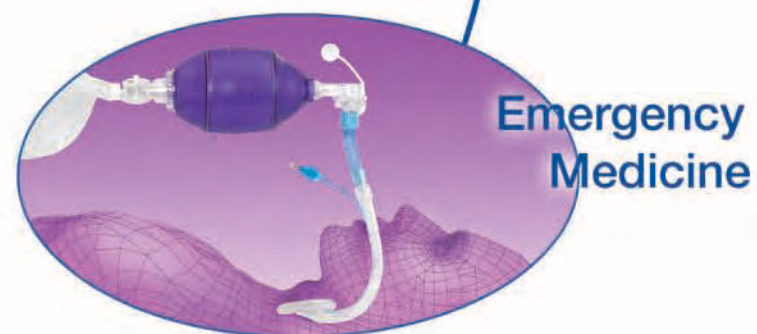
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We will be happy to put you in touch with your nearest distributor.

Additional information is available at
www.smiths-medical.com

1

Intubation

The quality and variety of the Smiths Medical range of disposable intubation products has placed the company firmly among the leading suppliers of consumables for general anaesthesia.

Our varied range, including over 250 different endotracheal tubes alone, provides a choice of design, material, size and accessories to meet almost every anaesthetic requirement.

The range includes standard Magill tubes, polar preformed tubes and a range of specialised tubes in a choice of clear, siliconised or ivory PVC, polyurethane and silicone.

The Endotracheal range is complemented by a wide range of accessories, including tube introducers, guides, stylets and holders.

Endotracheal tubes - the material you prefer

Smiths Medical offers a variety of materials to suit the majority of clinical needs.

Clear PVC



Siliconised PVC



Ivory PVC



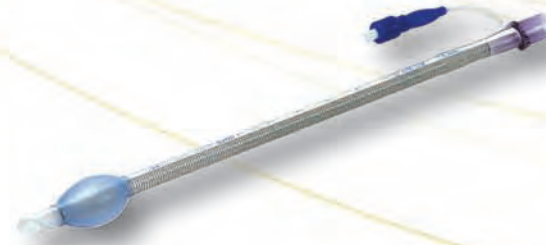
Reinforced PVC*



Polyurethane



Silicone



Endotracheal tubes - the choice of cuff to meet your clinical needs

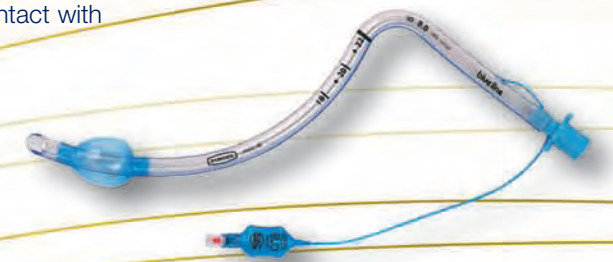
Profile Soft Seal cuff

- Combines all the benefits of the Profile cuff design with a larger cuff resting diameter
- Low pressure, high volume cuff for minimal trauma whilst providing an effective seal
- Soft material
- When deflated cuff relaxes smoothly to tube minimising discomfort on insertion and removal
- Clear markings on pilot balloon provide relevant information



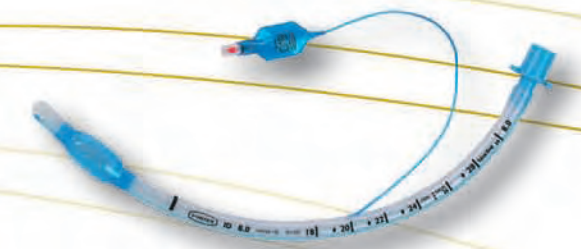
Profile cuff

- Smooth, tapered membrane cuff shape ensures minimum contact with the sensitive tracheal mucosa
- Reduces movement relative to trachea during ventilation
- Low pressure - responds rapidly to varying pressures during the respiratory cycle
- Streamlined shape reduces risk of creasing on inflation and minimises pressure on tracheal wall
- When deflated cuff conforms closely to tube for trauma-free intubation and extubation
- Clear markings on pilot balloon provide relevant information



Traditional cuff

- Permits complete airway control for short-term intubation
- Clear markings on pilot balloon provide relevant information



The Soft Seal Laryngeal Mask

The single-use Portex Soft Seal Laryngeal Mask is an important addition to the Smiths Medical portfolio of intubation products offering the following benefits to clinicians:

- Better infection control - research has shown that however thoroughly reusable airway devices are cleaned, there still may be residual protein deposits which have the potential for disease transmission¹.

*"...our findings prompt us to seriously question the safety of re-using instruments such as the laryngeal mask airway...Even following the guidelines for cleaning this equipment may be insufficient to protect patients from transmission of iatrogenic disease."*¹

With the single-use Soft Seal Laryngeal Mask, all possibility of between-patient cross-infection is eliminated.

- Ease of access - The Soft Seal Laryngeal Mask has been designed to remove the need for epiglottis bars, allowing ease of access for fibre optic devices and the fibre optic guided placement of endotracheal tubes.
- A clear view - With the translucent tubing of the Soft Seal Laryngeal Mask condensation is clearly visible to confirm correct mask placement.



- Smooth design allows easy insertion and positioning. The integral inflation line reduces the risk of damage to the line and of trauma to the patient's oropharyngeal mucosa.
- The Portex Soft Seal cuff minimises the rise in cuff pressure seen with other materials^{2,3}, minimising the risk of potential trauma to the patient's oropharynx.



Ordering information

Soft Seal Laryngeal Mask

Description	I.D. (mm)	O.D. (mm)	Maximum Cuff Volume (ml)	Size	Pack Qty	Product Code
Neonates/infants up to 5kg	5.3	7.8	6	1.0	10	100/220/100
Infants 5-10kg	6.1	9.5	8	1.5	10	100/220/150
Infants/children 10-20kg	7.1	11.3	12	2.0	10	100/220/200
Children 20-30kg	8.5	13.1	17	2.5	10	100/220/250
Children 30-50kg	10.1	15.3	25	3.0	10	100/220/300
Adults 50-70kg	11.0	17.6	35	4.0	10	100/220/400
Adults 70kg+	12.0	19.8	55	5.0	10	100/220/500

INTUBATION

References: 1 Miller D.M, Youkhana I, Karunatne W.U, Pearce A. Presence of Protein deposits on 'cleaned' re-usable anaesthetic equipment. Anaesthesia, 2001; **56**: 1069-1072

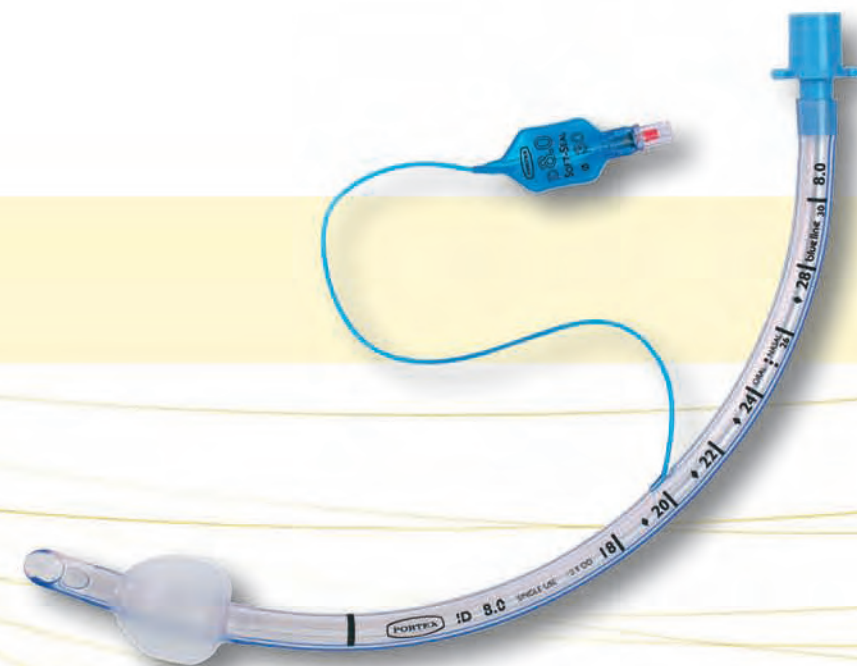
2 Lumb, A.B, Wrigley M.W, The effect of nitrous oxide on laryngeal mask cuff pressure. In vitro and in vivo studies. Anaesthesia, 1992, **47**: 320-3

3 Bench test data on file

Magill Tubes - Cuffed

Oral/nasal tube, Clear PVC, Profile Soft Seal cuff

- Murphy Eye smoothly formed to reduce mucosal damage
- Black intubation depth marker located 3cm proximal to the cuff to assist accurate placement of tube tip within the trachea
- Sensitive pilot balloon gives assurance of cuff inflation and indicates Soft Seal cuff in situ, together with tube size and cuff resting diameter



Ordering information

I.D. (mm)	O.D. (mm)	Cuff resting diameter (mm)	Pack Qty	Product Code
5.0	6.8	17	20	100/199/050
5.5	7.4	17	20	100/199/055
6.0	8.2	23	20	100/199/060
6.5	8.8	23	20	100/199/065
7.0	9.6	30	20	100/199/070
7.5	10.2	30	20	100/199/075
8.0	11.0	30	20	100/199/080
8.5	11.6	30	20	100/199/085
9.0	12.3	30	20	100/199/090
9.5	13.0	30	20	100/199/095
10.0	13.7	34	20	100/199/100

Magill Tubes - Cuffed

Oral/nasal tube, Siliconised PVC, Profile Soft Seal cuff

- Siliconised for easy intubation and passage of suction catheters
- Black intubation depth marker located 3cm proximal to the cuff to assist accurate placement of tube tip within the trachea
- Sensitive pilot balloon gives assurance of cuff inflation and indicates Soft Seal cuff in situ, together with tube size and cuff resting diameter.

Ordering information

I.D. (mm)	O.D. (mm)	Cuff resting diameter (mm)	Pack Qty	Product Code
5.0	6.8	17	10	100/166/050
5.5	7.4	17	10	100/166/055
6.0	8.2	23	10	100/166/060
6.5	8.8	23	10	100/166/065
7.0	9.6	30	10	100/166/070
7.5	10.2	30	10	100/166/075
8.0	11.0	30	10	100/166/080
8.5	11.6	30	10	100/166/085
9.0	12.3	30	10	100/166/090
9.5	13.0	30	10	100/166/095
10.0	13.6	32	10	100/166/100



Oral/nasal tube, Siliconised PVC, Traditional cuff

- Kink-resistant, minimising possibility of tube occlusion
- Black intubation depth marker located 3cm proximal to the cuff to assist accurate placement of tube tip within the trachea
- Pilot balloon indicates tube size

Ordering information

I.D. (mm)	O.D. (mm)	Cuff resting diameter (mm)	Pack Qty	Product Code
5.0	6.9	-	20	100/162/050
5.5	7.6	-	20	100/162/055
6.0	8.2	-	20	100/162/060
6.5	8.9	-	20	100/162/065
7.0	9.6	-	20	100/162/070
7.5	10.3	-	20	100/162/075
8.0	10.9	-	20	100/162/080
8.5	11.6	-	20	100/162/085
9.0	12.3	-	20	100/162/090
9.5	13.0	-	20	100/162/095
10.5	14.4	-	20	100/162/105
11.0	15.0	-	20	100/162/110



Magill Tubes - Cuffed

Nasal tube, Ivory PVC, Profile Soft Seal cuff

- Comprehensive size range to suit adolescent and adult tracheal sizes
- Black intubation depth marker located 3cm proximal to the cuff to assist accurate placement of tube tip within the trachea
- Sensitive pilot balloon gives assurance of cuff inflation and indicates Soft Seal cuff in situ, together with tube size and cuff resting diameter.

Ordering information

I.D. (mm)	O.D. (mm)	Cuff resting diameter (mm)	Pack Qty	Product Code
5.0	7.3	17	10	100/179/050
5.5	8.0	17	10	100/179/055
6.0	8.8	23	10	100/179/060
6.5	9.5	23	10	100/179/065
7.0	10.2	30	10	100/179/070
7.5	10.9	30	10	100/179/075
8.0	11.6	30	10	100/179/080
8.5	12.4	30	10	100/179/085
9.0	13.1	30	10	100/179/090



Oral/Nasal tube, Ivory PVC, Traditional cuff

- Kink-resistant, minimising possibility of tube occlusion
- Black intubation depth marker located 3cm proximal to the cuff to assist accurate placement of tube tip within the trachea
- Pilot balloon indicates tube size

Ordering information

I.D. (mm)	O.D. (mm)	Pack Qty	Product Code
5.0	7.3	20	100/174/050
5.5	8.0	20	100/174/055
6.0	8.8	20	100/174/060
6.5	9.5	20	100/174/065
7.0	10.2	20	100/174/070
7.5	10.9	20	100/174/075
8.0	11.6	20	100/174/080
8.5	12.4	20	100/174/085
9.0	13.1	20	100/174/090
9.5	13.8	20	100/174/095*
10.0	14.3	20	100/174/100*
10.5	14.8	20	100/174/105*
11.0	15.4	20	100/174/110*



Ivory PVC Oral/Nasal tube also available with profile cuff in sizes 5-10, including all half sizes. Ordering code is 100/178/***

Magill Tubes - Uncuffed

Blue Line, Siliconised PVC, Oral/Nasal, Uncuffed

- 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 Blue Line 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



Ordering information

I.D. (mm)	O.D. (mm)	Pack Qty	Product Code
2.0	2.9	10	100/111/020
2.5	3.4	10	100/111/025
3.0	4.2	10	100/111/030
3.5	4.8	10	100/111/035
4.0	5.4	10	100/111/040
4.5	6.2	10	100/111/045
5.0	6.9	10	100/111/050
5.5	7.6	10	100/111/055
6.0	8.2	10	100/111/060
6.5	8.9	10	100/111/065
7.0	9.6	10	100/111/070
7.5	10.3	10	100/111/075
8.0	10.9	10	100/111/080
8.5	11.6	10	100/111/085
9.0	12.3	10	100/111/090
9.5	13.0	10	100/111/095
10.0	13.6	10	100/111/100
10.5	14.4	10	100/111/105*
11.0	15.0	10	100/111/110*

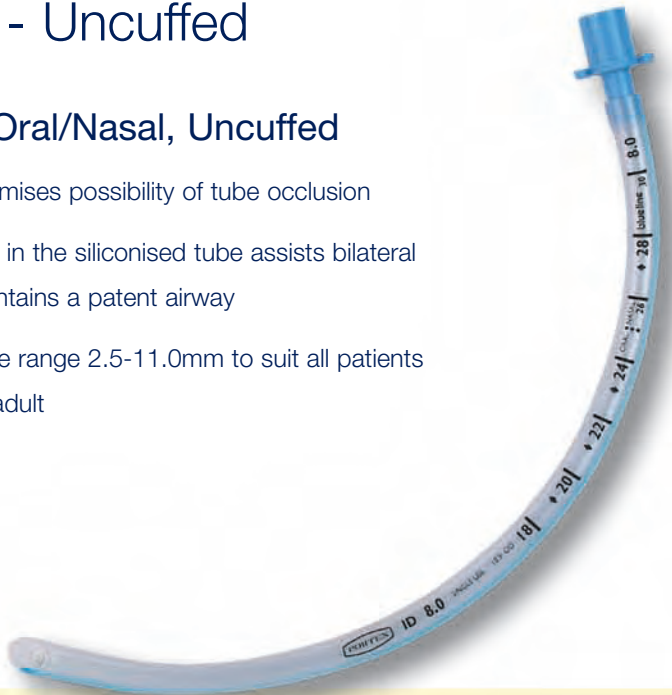
* Please Note: These items are made to order only, please contact Customer Services with regard to lead time.

* Please Note: These items are made to order only, please contact Customer Services with regard to lead time.

Magill Tubes - Uncuffed

Siliconised PVC, Oral/Nasal, Uncuffed

- Kink-resistant, minimises possibility of tube occlusion
- Murphy eye design in the siliconised tube assists bilateral ventilation and maintains a patent airway
- Comprehensive size range 2.5-11.0mm to suit all patients from paediatric to adult



Ordering information

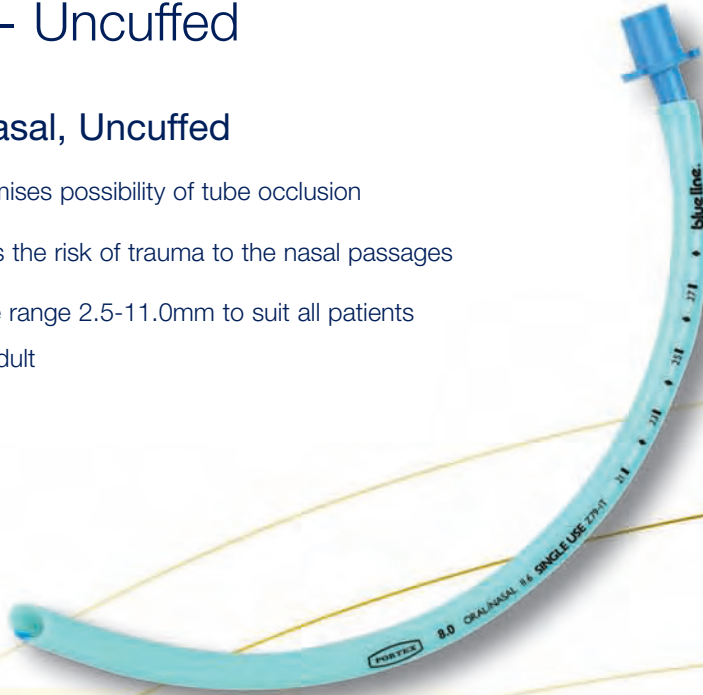
I.D. (mm)	O.D. (mm)	Pack Qty	Product Code
2.5	3.4	10	100/141/025
3.0	4.2	10	100/141/030
3.5	4.8	10	100/141/035
4.0	5.5	10	100/141/040
4.5	6.2	10	100/141/045
5.0	6.9	10	100/141/050
5.5	7.6	10	100/141/055
6.0	8.2	10	100/141/060
6.5	8.9	10	100/141/065
7.0	9.6	10	100/141/070
7.5	10.3	10	100/141/075
8.0	10.9	10	100/141/080*
8.5	11.6	10	100/141/085*
9.0	12.3	10	100/141/090*
9.5	13.0	10	100/141/095*
10.0	13.7	10	100/141/100*
10.5	14.4	10	100/141/105*
11.0	15.0	10	100/141/110*

* Please Note: These items are made to order only, please contact Customer Services with regard to lead time.

Magill Tubes - Uncuffed

Ivory PVC, Oral/Nasal, Uncuffed

- Kink-resistant, minimises possibility of tube occlusion
- Ivory PVC minimises the risk of trauma to the nasal passages
- Comprehensive size range 2.5-11.0mm to suit all patients from paediatric to adult



Ordering information

I.D. (mm)	O.D. (mm)	Pack Qty	Product Code
2.5	3.6	10	100/105/025
3.0	4.4	10	100/105/030
3.5	5.0	10	100/105/035
4.0	5.8	10	100/105/040
4.5	6.6	10	100/105/045
5.0	7.3	10	100/105/050
5.5	8.0	10	100/105/055
6.0	8.8	10	100/105/060
6.5	9.5	10	100/105/065
7.0	10.2	10	100/105/070
7.5	10.9	10	100/105/075
8.0	11.6	10	100/105/080
8.5	12.4	10	100/105/085
9.0	13.1	10	100/105/090*
9.5	13.8	10	100/105/095*
10.0	14.3	10	100/105/100*

* Please Note: These items are made to order only, please contact Customer Services with regard to lead time.

Paediatric & Neonatal Tubes

Cole's Neonatal Tube

- For resuscitation and ventilation of neonates
- Manufactured from clear, non-toxic PVC to protect delicate mucosal tissues
- Tapered internally to allow suction catheters to pass freely
- Choice of 6 sizes to suit all neonates from premature to full-term
- Available with and without holder

Ordering information

I.D. (mm)	Pack Qty	(without holder) Reference Code	Holder Product Code
1.5	10	100/430/150	100/431/015
2.0	10	100/430/200	100/431/020
2.5	10	100/430/250	100/431/025
3.0	10	100/430/300	100/431/030
3.5	10	100/430/350	100/431/035
4.0	10	100/430/400	100/431/040



Croup Tube, Paediatric, Siliconised PVC, Extra Long, Oral/Nasal, Uncuffed

- Extra long tracheal tube designed to minimise 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

Ordering information

I.D. (mm)	O.D. (mm)	Length (mm)	Pack Qty	Product Code
2.5	3.5	220	10	100/112/025*
3.0	4.2	250	10	100/112/030*
3.5	4.8	280	10	100/112/035*
4.0	5.5	310	10	100/112/040*
4.5	6.2	330	10	100/112/045*
5.0	6.8	330	10	100/112/050*

* Please Note: These items are made to order only, please contact Customer Services with regard to lead time.



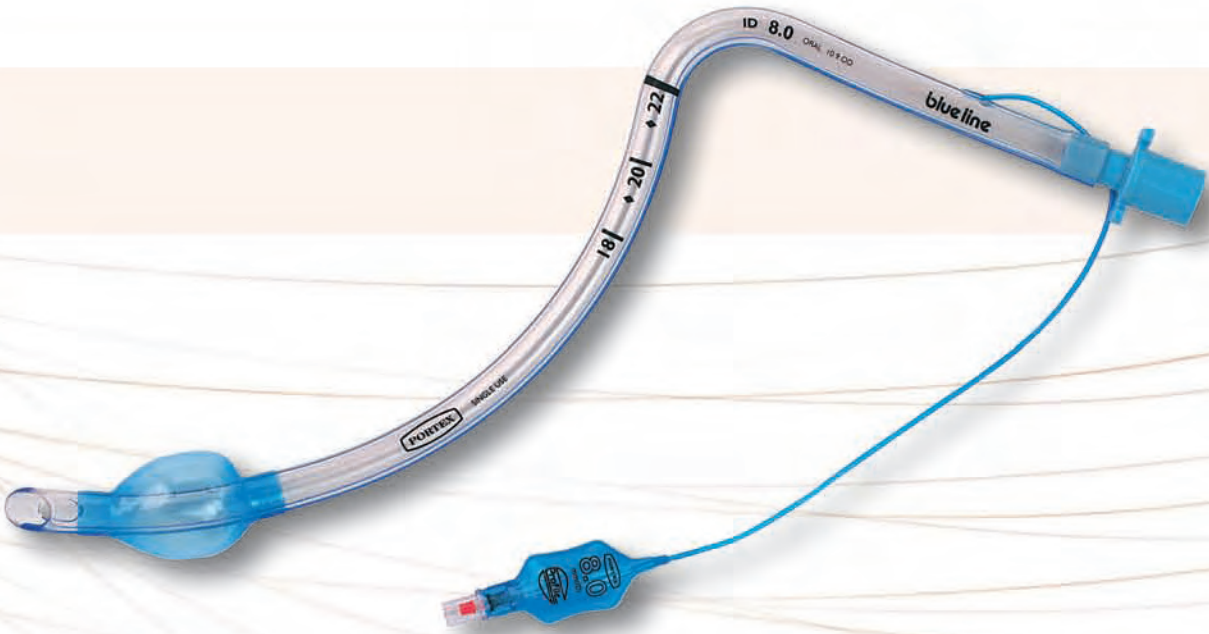
2 Intubation Specialist Tubes

All Smiths Medical Intubation Specialist Tubes are manufactured to the highest quality standards, specifically for specialised clinical needs. Available cuffed and uncuffed, polar preformed, reinforced or in silicone to suit individual clinician's requirements.

Polar Preformed Tubes - Cuffed

Cuffed North Oral Polar Tube, Clear PVC

- Smooth, preformed bend, gently curves the tube towards the patient's forehead, where it can be conveniently secured and connected to the breathing system
- Elimination of an angled connector and catheter mount reduces the risk of disconnection from the breathing system
- Inflation line exit positioned on the external limb of the tube to permit uninterrupted visibility during intubation, as well as protection of the inflation line from damage by teeth
- The Portex Profile Cuff is a low pressure cuff designed to minimise tracheal trauma. Good aspiration protection is provided by avoiding the folding associated with larger diameter cuffs



Ordering information

I.D. (mm)	O.D. (mm)	Tip to Incisor Teeth Length (cm)	Pack Qty	Product Code
6.0	8.2	18.0	10	100/131/060
6.5	8.8	19.0	10	100/131/065
7.0	9.6	20.0	10	100/131/070
7.5	10.2	21.0	10	100/131/075
8.0	11.0	22.0	10	100/131/080
8.5				
11.6				

Polar Preformed Tubes - Cuffed

Cuffed North Nasal Polar Tube, Ivory PVC

- The design ensures access to the face allowing the surgeon to observe the effect of manipulation of the maxilla on facial symmetry
- Clear markings at the levels of the vocal cords and nares assist correct placement
- A black intubation depth marker is located 3cm proximal to the cuff. This assists the accurate placement of the tracheal tube tip within the trachea
- The PROFILE SOFT SEAL cuff is made from soft PVC material, minimising the risk of trauma
- Larger cuff resting diameter ensures effective seal in both male and female patients, even when selecting smaller bore tracheal tubes

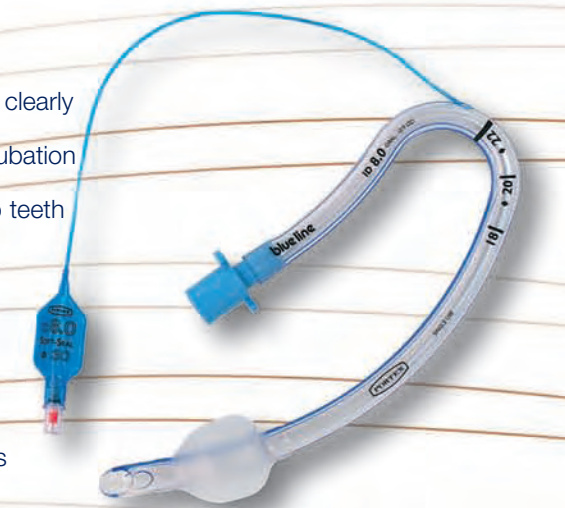


Ordering information

Tip to Nares I.D. (mm)	O.D. (mm)	Cuff Resting Length (cm)	Diameter (mm)	Pack Qty	Product Code
6.0	8.8	27.0	23	10	100/133/060
6.5	9.4	27.5	23	10	100/133/065
7.0	10.2	28.5	30	10	100/133/070
7.5	10.8	29.5	30	10	100/133/075
8.0	11.6	30.5	30	10	100/133/080

Cuffed South Oral Polar Tube, Clear PVC

- Clear tube allows moisture condensation from the breath to be seen clearly
- Murphy eye smoothly formed to avoid vocal cord damage during intubation
- Inflation line take-off point lies outside the mouth to avoid damage to teeth
- South limb curved to avoid pressure on the chin and lower lip
- The PROFILE SOFT SEAL cuff is made from soft PVC material, minimising the risk of trauma
- Larger cuff resting diameter ensures effective seal in both male and female patients, even when selecting smaller bore tracheal tubes
- A black intubation depth marker is located 3cm proximal to the cuff. This assists the accurate placement of the tracheal tube tip with the trachea



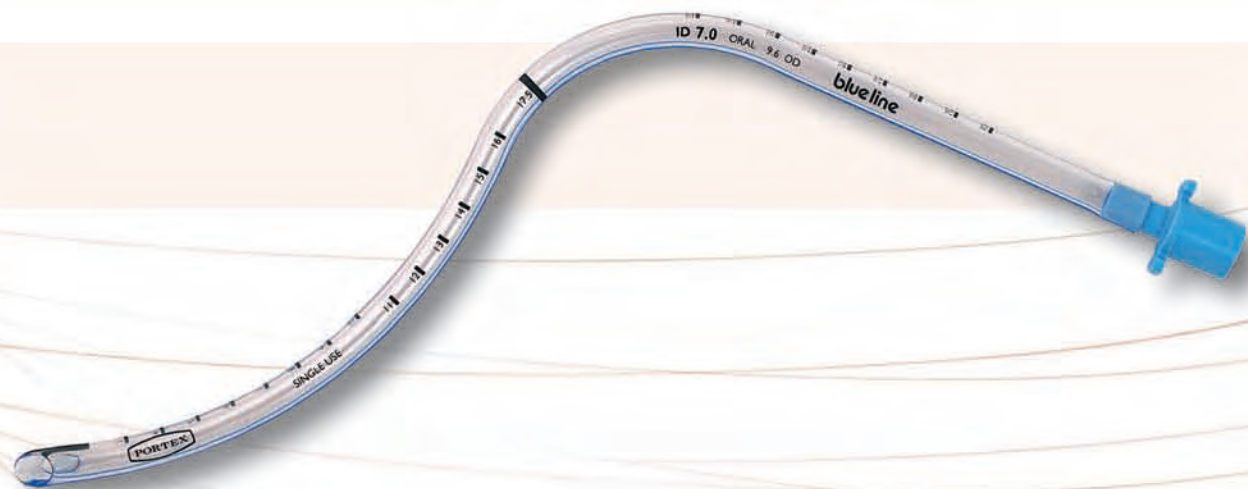
Ordering information

I.D. (mm)	O.D. (mm)	Tip to Incisor Teeth Length (cm)	Cuff Resting Diameter (mm)	Pack Qty	Product Code
5.0	6.8	16	17	10	100/136/050
5.5	7.4	17	17	10	100/136/055
6.0	8.2	18	23	10	100/136/060
6.5	8.8	19	23	10	100/136/065
7.0	9.6	20	30	10	100/136/070
7.5	10.2	21	30	10	100/136/075
8.0	11.0	22	30	10	100/136/080
8.5	11.6	23	30	10	100/136/085
9.0	12.2	24	30	10	100/136/090

Polar Preformed Tubes - Uncuffed

Uncuffed North Oral Polar Tube, Clear PVC

- “North” facing limb provides excellent fixation points ensuring greater tube stability
- Long incisor to 15mm connector length provides the opportunity to cut-to-length to meet individual requirements
- 1cm graduations on both sides of the tracheal tube facilitate identification of the tracheal tube position
- Murphy Eye smoothly formed to avoid vocal cord damage through intubation
- Clear, thermosensitive PVC softens at body temperature and allows the tube to conform to the shape of the airway



Ordering information

I.D. (mm)	O.D. (mm)	Tip to Incisor Length (cm)	Pack Qty	Product Code
3.0	4.2	10.5	10	100/132/030
3.5	4.8	11.0	10	100/132/035
4.0	5.4	12.0	10	100/132/040
4.5	6.2	13.5	10	100/132/045
5.0	6.8	14.0	10	100/132/050
5.5	7.4	14.5	10	100/132/055
6.0	8.2	15.0	10	100/132/060
6.5	8.8	16.0	10	100/132/065
7.0	9.6	17.5	10	100/132/070

Polar Preformed Tubes - Uncuffed

Uncuffed North Nasal Polar Tube - Polyurethane

- Polyurethane material has good kink-resistant properties, making it particularly appropriate for oral surgery
- Soft and flexible for atraumatic intubation and extubation, minimising damage to delicate nasal mucosa
- Polyurethane tube retains its shape at body temperature, allowing ease of intubation through the nasopharyngeal area
- Transparent tube allows breath condensation to be visualised, enabling the anaesthetist to quickly check correct tube placement
- Preformed north facing shape reduces the number of connections, thereby maximising safety whilst improving surgical access



Ordering information

I.D. (mm)	O.D. (mm)	Tip to Nares Length (cm)	Pack Qty	Product Code
6.0	8.2	27.0	10	100/130/060
6.5	8.8	27.5	10	100/130/065
7.0	9.6	28.5	10	100/130/070
7.5	10.3	29.5	10	100/130/075
8.0	11.0	30.5	10	100/130/080

Uncuffed South Oral Polar Tube, Clear PVC

- South limb curved to avoid pressure on the chin and lower lip
- Intubating length (tip to incisor teeth identification mark) conforms to cut-to-length norms
- 1cm graduations on both sides of the tracheal tube assist positioning of tube past the vocal cords
- Clear, thermosensitive PVC softens at body temperature and allows the tube to conform to the shape of the airway
- Murphy Eye smoothly formed to avoid vocal cord damage during intubation



Ordering information

I.D. (mm)	O.D. (mm)	Tip to Incisor Length (cm)	Pack Qty	Product Code
3.0	4.2	10.5	10	100/134/030
3.5	4.8	11.0	10	100/134/035
4.0	5.4	12.0	10	100/134/040
4.5	6.2	13.5	10	100/134/045
5.0	6.8	14.0	10	100/134/050
5.5	7.5	14.5	10	100/134/055
6.0	8.2	15.0	10	100/134/060
6.5	8.8	16.0	10	100/134/065
7.0	9.6	17.5	10	100/134/070
7.5	10.2	19.0	10	100/134/075

Reinforced ET Tubes

Reusable Reinforced, Oral/Nasal, Silicone

- Wire reinforcing reduces risk of kinking under extreme conditions
- Silicone rubber construction allows multiple tube reuse by autoclaving
- The range of uncuffed tubes covers paediatric sizes

Ordering information

I.D. (mm)	Pack Qty	Plain Uncuffed Product Code	Cuffed, Magill Product Code	Cuffed, Murphy Eye Product Code
2.5	2	100/107/025	-	-
3.0	2	100/107/030	-	-
3.5	2	100/107/035	-	-
4.0	2	100/107/040	-	-
4.5	2	100/107/045	-	-
5.0	2	100/107/050	-	100/109/050
5.5	2	-	-	100/109/055
6.0	2	100/107/060	100/108/060	100/109/060
6.5	2	-	-	100/109/065
7.0	2	100/107/070	100/108/070	100/109/070
7.5	2	-	-	100/109/075
8.0	2	100/107/080	100/108/080	100/109/080
8.5	2	-	-	100/109/085
9.0	2	-	100/108/090	100/109/090
9.5	2	-	-	100/109/095

Single Use Reinforced, Oral/Nasal, PVC

- Available cuffed or uncuffed
- Cuffed tubes feature Murphy eye and Soft Seal cuff
- Smoothly finished tube tip and cuff welds for ease of intubation and extubation
- Flexible to conform to patient position
- Spiral reinforcement minimises crushing or kinking

Ordering information

I.D. (mm)	Pack Qty	Uncuffed Product Code	Cuffed Product Code
3.0	5	100/113/030	-
3.5	5	100/113/035	-
4.0	5	100/113/040	-
4.5	5	100/113/045	-
5.0	5	100/113/050	100/110/050
5.5	5	-	100/110/055
6.0	5	-	100/110/060
6.5	5	-	100/110/065
7.0	5	-	100/110/070
7.5	5	-	100/110/075
8.0	5	-	100/110/080
8.5	5	-	100/110/085
9.0	5	-	100/110/090
9.5	5	-	100/110/095

Reinforced ET Tubes - Bivona

Mid-Range Aire-Cuf® Wire Reinforced Silicone Endotracheal Tube

- Murphy Eye
- Low pressure cuff design
- Kink resistant
- Improved patient comfort and safety
- Soft, low trauma tip
- 15mm ISO connector

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
6.0	8.7	28	10	75W060
6.5	9.4	28	10	75W065
7.0	10.0	30	10	75W070
7.5	10.4	30	10	75W075
8.0	11.0	31	10	75W080
8.5	11.8	31	10	75W085
9.0	12.3	31	10	75W090
9.5	13.3	31	10	75W095

Small Diameter Aire-Cuf® Wire Reinforced Silicone Endotracheal Tube

- Murphy Eye
- Integral stainless steel reinforcing wire provides a safe, kink resistant airway regardless of position of neck or head or manipulation of the tube
- Improves patient comfort and safety
- Soft, low trauma tip
- 15mm ISO connector

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code ¹	Product Code ²	Product Code ³
2.5	4.0	14	10	-	-	35W025 ^B
3.0	4.7	16	10	-	-	35W030
3.5	5.3	18	10	-	-	35W035
4.0	6.0	20	10	-	-	35W040
4.5	6.7	22	10	-	-	35W045
5.0	7.3	24	10	-	-	35W050
5.5	8.0	26	10	-	-	35W055
6.0	8.7	28	10	20W060 ^A	25W060 ^A	35W060 ^A
6.5	9.4	28	10	20W065	25W065 ^A	35W065 ^A
7.0	10.0	30	10	20W070	25W070	35W070
7.5	10.4	30	10	20W075	25W075	35W075
8.0	11.0	31	10	20W080	25W080	35W080
8.5	11.8	31	10	20W085	25W085	35W085
9.0	12.3	31	10	20W090	25W090	35W090
9.5	13.3	31	10	20W095	25W095	35W095

1) All codes include Murphy eye and inflation plug
2) All codes include Murphy eye and inflation valve
3) All codes include Magill tip and inflation valve
A) Adult sizes have a small diameter Aire-Cuf®
B) Paediatric sizes TTS™ have a clear pilot balloon and TTS™ cuff



Reinforced ET Tubes - Bivona

Cuffless Wire Reinforced Silicone Endotracheal Tube

- Integral stainless steel reinforcing wire provides a safe, kink resistant airway regardless of position of neck or head or manipulation of the tube
- Improves patient comfort and safety
- Soft, low trauma tip
- 15mm ISO connector
- Easily identified by the black print and cuffless designation on the shaft

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
2.5	4.0	14	10	15W025
3.0	4.7	16	10	15W030
3.5	5.3	18	10	15W035
4.0	6.0	20	10	15W040
4.5	6.7	22	10	15W045
5.0	7.3	24	10	15W050
5.5	8.7	28	10	15W055
6.0	8.7	28	10	15W060*
6.5	9.4	28	10	15W065*
7.0	10.0	30	10	15W070*
7.5	10.4	30	10	15W075*
8.0	11.0	31	10	15W080*
8.5	11.8	31	10	15W085*
9.0	12.3	31	10	15W090*
9.5	13.3	31	10	15W095*

*Special order item; minimum order 100 units per size, and 6 -10 weeks delivery.



Silicone ET Tubes - Bivona

Fome-Cuf® Endotracheal Tube Kit with SidePort™ AutoControl™ Airway Connector and CMD™

- Automatically adjusts to changes in the trachea
- Reduced risk of tracheal dilation due to innovative design of cuff
- Improved patient comfort and safety
- 15mm ISO connector

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
6.0	8.7	28	10	800160
6.5	9.4	28	10	800165
7.0	10.0	30	10	800170
7.5	10.4	30	10	800175
8.0	11.0	31	10	800180
8.5	11.8	31	10	800185
9.0	12.3	31	10	800190
9.5	13.3	31	10	800195



Fome-Cuf® Wire Reinforced Endotracheal Tube Kit with SidePort™ AutoControl™ Airway Connector and CMD™

- Kink resistant
- Reduced risk of tracheal dilation due to innovative design of cuff
- Improved patient comfort and safety
- 15mm ISO connector

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
6.0	8.7	8	10	80W160
7.0	10.0	30	10	80W170
8.0	11.0	31	10	80W180
9.0	12.3	31	10	80W190



Silicone ET Tubes - Bivona

Small Diameter Aire-Cuf® Endotracheal Tube

- Murphy Eye
- Improved patient comfort and safety
- Soft, low trauma tip
- 15mm ISO connector

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
6.0	8.7	29	10	250060
6.5	9.4	30	10	250065
7.0	10.0	31	10	250070
7.5	10.4	32	10	250075
8.0	11.0	33	10	250080
8.5	11.8	33	10	250085
9.0	12.3	33	10	250090
9.5	13.3	33	10	250095



Mid-Range Aire-Cuf® Endotracheal Tube

- Murphy Eye
- Low pressure cuff design
- Improved patient comfort and safety
- Soft, low trauma tip
- 15mm ISO connector

Ordering information

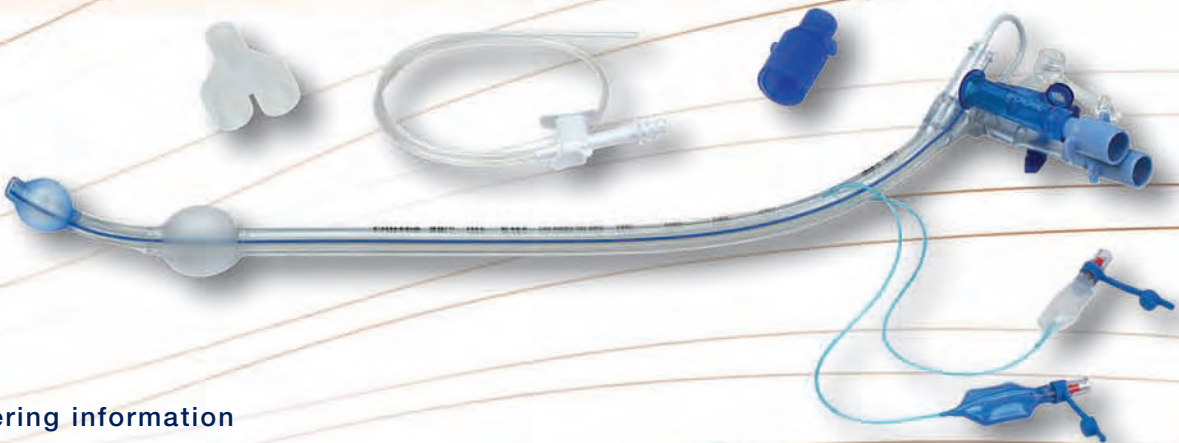
I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
6.0	8.7	29	10	750060
6.5	9.4	30	10	750065
7.0	10.0	31	10	750070
7.5	10.4	32	10	750075
8.0	11.0	33	10	750080
8.5	11.8	33	10	750085
9.0	12.3	33	10	750090
9.5	13.3	33	10	750095



Endobronchial Tubes

Smiths Medical Endobronchial Tubes have been specifically designed with many features to enhance user technique and patient safety:

- The unique right-angle circuit takeoff minimises torque on the endobronchial tube and directs the circuit up and over the patient's head
- Manufactured from thermosensitive clear PVC, the endobronchial tube softens at body temperature. This minimises the risk of trauma to the tracheal mucosa.
- The Carlens-Style wye adaptor allows selective lung ventilation, differential lung ventilation and CPAP.
- A bevelled tip and Soft Seal® high-volume/low-pressure cuff system minimises risk of intubation airway trauma
- Colour coded adapters and pilot balloons help ease of use and enable quick identification of cuff inflation status
- Blue cuff aids in verification of placement, the larger lumen allows use of larger fibre-optic bronchoscopes and suction catheters
- Engineered for more safety, the Profile® Soft Seal® cuff minimises tracheal wall contact



Ordering information

FR Size	Type	Pack Qty	Product Code
28.0	Left Bronchus	1	198-28L
32.0	Left Bronchus	1	198-32L
35.0	Left Bronchus	1	198-35L
37.0	Left Bronchus	1	198-37L
39.0	Left Bronchus	1	198-39L
41.0	Left Bronchus	1	198-41L
28.0	Right Bronchus	1	197-28R
32.0	Right Bronchus	1	197-32R
35.0	Right Bronchus	1	197-35R
37.0	Right Bronchus	1	197-37R
39.0	Right Bronchus	1	197-39R
41.0	Right Bronchus	1	197-41R

Specialist Tubes

Microlaryngeal Tube

- Manufactured from smooth, Ivory PVC to protect delicate mucosal tissues
- Flexible and kink-resistant to minimise risk of tube occlusion
- Oral/nasal design to meet clinical requirements
- Profile cuff design to minimise the potential for trauma to the trachea
- Black intubation depth marker located 3cm proximal to the cuff assists the accurate placement of the tracheal tube tip within the trachea



Ordering information

I.D. (mm)	O.D. (mm)	Pack Qty	Product Code
5.0	7.2	10	100/190/050

Microlaryngeal Tube - Bivona

- Kink resistant
- Small size affords a better view of the laryngeal area
- Soft, low trauma tip
- 15mm ISO connector



Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
5.0	7.3	32	10	65W050

Includes Magill Tip and inflation valve

Specialist Tubes

TTS™ Carden Laryngoscopy Tube - Bivona

- Soft, low trauma tip
- Soft silicone cuff reduces trauma to tracheal lining

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	FG	Pack Qty	Product Code
6.0	8.7	43	26	10	CARL60
7.0	10.0	43	30	10	CARL70
8.0	11.0	43	33	10	CARL80



Specialist Tubes

TTS™ Carden Bronchoscopy Tube - Bivona

- Soft, low trauma tip
- Soft silicone cuff reduces trauma to tracheal lining
- 15mm ISO connector and swivel connector, fiberoptic cap

Ordering information

I.D. (mm)	O.D. (mm)	Length (cm)	FR	Pack Qty	Product Code
8.0	11	29	33	10	CARB80
8.5	11.8	29	35	10	CARB85
9.0	12.3	37	37	10	CARB90

Siliconised PVC, Oral/Nasal, Gas Monitoring Line, Profile Cuff

- When coupled to an analyser, end-tidal CO₂ monitoring is simply and accurately achieved by a non-invasive and continuous technique
- The capped white luer termination permits a gas tight connection and allows the line to be securely closed when not required
- The 2.0mm lumen of the gas monitoring line allows optimum flow rates giving quick response times essential for accurate readings
- A black intubation depth marker is located 3cm proximal to the cuff. This assists the accurate placement of the tracheal tube tip within the trachea

Ordering information

I.D. (mm)	O.D. (mm)	Pack Qty	Product Code
7.5	10.3	10	100/196/075
8.0	11.0	10	100/196/080
8.5	11.6	10	100/196/085
9.0	12.2	10	100/196/090

Uncuffed Neonatal/Paediatric Endotracheal Tubes

- 15mm ISO connector and swivel connector
- Smooth bevelled tube tip
- Low Dead Space Connector

Ordering information

Description	I.D. (mm)	Pack Qty	Product Code
Endotracheal Tube Connectors with Sideport			
Standard 15mm ISO Connector with Sideport	2.5	10	H4021S
Standard 15mm ISO Connector with Sideport	3.0	10	H4022S
Standard 15mm ISO Connector with Sideport	3.5	10	H4023S
Standard 15mm ISO Connector with Sideport	4.0	10	H4024S
Standard 15mm ISO Connector with Sideport	4.5	10	H4025S
Standard 15mm ISO Connector with Sideport	5.0	10	H4026S
Low Dead Space 15mm ISO Connector with Sideport	2.5	10	H4021PS
Low Dead Space 15mm ISO Connector with Sideport	3.0	10	H4022PS
Low Dead Space 15mm ISO Connector with Sideport	3.5	10	H4023PS

Airways

Airways - Disposable

- Design of nylon bite-block facilitates passage of a suction catheter
- Rigid bite-block to ensure airway integrity
- Smoothly rounded edges for improved patient comfort
- Comprehensive size range of 6 airways

Ordering information

Size	Length (cm)	Pack Qty	Product Code
00	5.0	50	100/320/200
0	6.0	50	100/320/100
1	7.0	50	100/320/010
2	9.0	50	100/320/020
3	10.0	50	100/320/030
4	11.0	50	100/320/040

Airway, Nasopharyngeal

- Maximum kink-resistance helps to ensure patent airway
- Smooth finish facilitates insertion
- Smoothly rounded edges for increased patient comfort
- Supplied with a safety pin in the pack for the option of an enlarged flange
- A choice of 4 sizes to suit most patients

Ordering information

I.D. (mm)	Pack Qty	Product Code
6.0	10	100/210/060
7.0	10	100/210/070
8.0	10	100/210/080
9.0	10	100/210/090



3

Intubation Accessories

Smiths Medical offers several simple solutions to difficult intubation through a comprehensive range of tracheal tube introducers, guides and stylets. The single-use range of introducers and guides have smoothly rounded tips, minimising trauma on insertion and include clear, graduated markings for ease of placement. The Smiths Medical intubation stylet is available in three sizes to fit the majority of adult and paediatric tracheal tubes and the paediatric tracheal tube holder ensures safe, simple and versatile fixation of the tracheal tube when ventilating neonates and infants.

Intubation Accessories

Tracheal Tube Holder, Paediatric

- Secure fixation to avoid risk of accidental extubation, disconnection or complete displacement of the tube
- Strong but lightweight and flexible to allow for normal movement of the head, whilst avoiding drag on circuit connections
- Maintains unimpeded access to the nose and mouth for nursing care, especially with the 15mm connector which facilitates the passage of suction catheters
- Cotton tapes are provided for secure fixation
- The extension tube can be used as a bite block or reversed to support the tracheal tube when connections are required away from the baby's face
- The extension tube may be shortened to suit the patient as required



Ordering information

Size (mm)	Pack Qty	Holder as a Separate Item with Tapes Product Code	Ivory PVC Oral/Nasal Tracheal Tube with Holder Product Code	Siliconised PVC Oral/Nasal Tracheal Tube with Holder Product Code
2.0	10	-	-	100/611/020
2.5	10	100/603/025	100/605/025	100/611/025
3.0	10	100/603/030	100/605/030	100/611/030
3.5	10	100/603/035	100/605/035	100/611/035
4.0	10	100/603/040	100/605/040	100/611/040
4.5	10	100/603/045	100/605/045	100/611/045

Individually double packed with 15mm connector inserted

Intubation Stylet, Tracheal Type

- Manufactured from malleable aluminium which allows the stylet to be easily adapted to any desired shape
- Smooth high density polyethylene outer sleeving permits easy insertion and withdrawal



Ordering information

O.D. (mm)	Effective Length (mm)	Recommended Tracheal Tube Sizes I.D (mm)	Pack Qty	Product Code
2.0	225	2.5-4.5	10	100/120/100
4.0	335	5.0-8.0	10	100/120/200
5.0	365	8.5-11.0	10	100/120/300
Extra Long Stylets				
4.0	673	5.0-8.0	10	100/121/200
5.0	693	8.5-11.0	10	100/121/300*

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

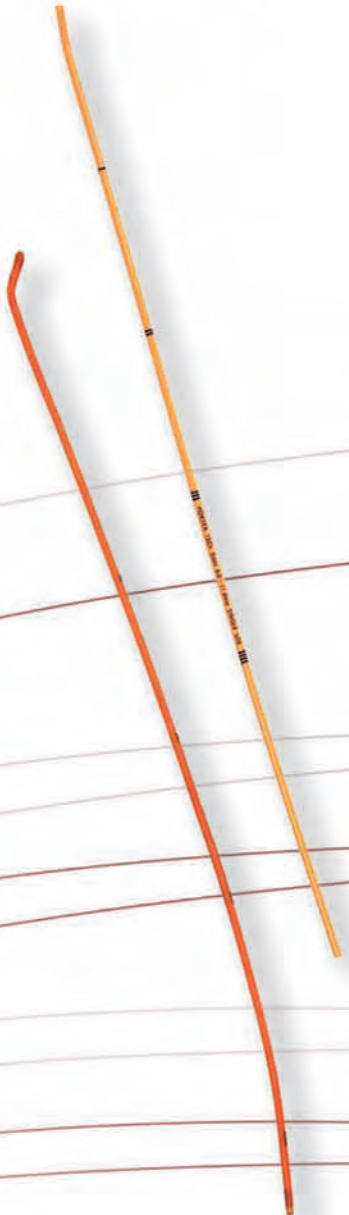
Intubation Accessories

Tracheal Tube Introducers and Guides

- The Introducer (coudé/angled tip) is designed to assist with tube placement during difficult intubations
- The Guide (straight tip) is designed to assist in tracheal tube exchange
- Product markings act as excellent indicators of intubation depth
- Size range provided facilitates use with tracheal tubes ranging from size 2.5mm to 11.0mm

Ordering information

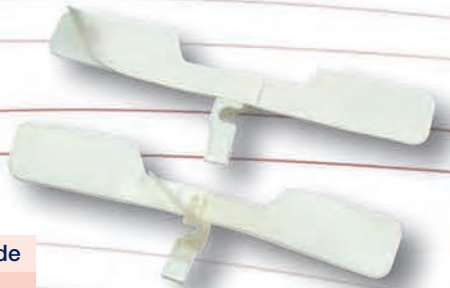
Description	Tip	Size	Length (mm)	Pack Qty	Product Code
Single use					
Introducer	Coudé	15Ch	600	10	100/125/515
Guide	Straight	5Ch	500	10	100/125/005
Guide	Straight	10Ch	700	10	100/125/010
Guide	Straight	15Ch	700	10	100/125/015
Reusable - "Bougie"					
Introducer	Coudé	15Ch	600	1	14-504-17
Guide	Straight	10Ch	700	1	14-504-76
Guide	Straight	15Ch	700	1	14-504-68



RSP® Endotracheal Tube holders

Provides secure tube fixation and have the advantage of readjustment or replacement without retaping

- Added security when you need it
- Convenience and safety
- Slide-on locking device eliminates the need for tape, pins or sutures



Ordering information

Description	I.D. (mm)	Pack Qty	Product Code
Neonatal/Paediatric Endotracheal Tube Holders			
	2.5	10	H4051
	3.0	10	H4052
	3.5	10	H4053
	4.0	10	H4054
	4.5	10	H4055
	5.0	10	H4056
Adult Endotracheal Tube Holders			
	4.5-6.5	30	K1000
	7.0-8.5	30	K2000
	9.0-10.0	30	K3000

Intubation Accessories

RSP® Neonatal/Paediatric Intubation Sytems and Components

The system consists of an endotracheal tube, holder and 15mm ISO connector

- Designed to ease the difficulties associated with neonatal intubation
- Murphy or Magill styles
- Smooth bevelled tip for atraumatic intubation
- 15mm ISO Sideport Connector
- Allows for the administration of medications and surfactants
- Safe, quick, and readjustable tube fixation



Ordering information

Description	I.D. (mm)	Pack Qty	Product Code
Neonatal/Paediatric Endotracheal Tube Holders			
Standard 15mm ISO Connector with Sideport; Tube Holder	2.5	10	H4001S
Standard 15mm ISO Connector with Sideport; Tube Holder	3.0	10	H4002S
Standard 15mm ISO Connector with Sideport; Tube Holder	3.5	10	H4003S
Standard 15mm ISO Connector with Sideport; Tube Holder	4.0	10	H4004S
Standard 15mm ISO Connector with Sideport; Tube Holder	4.5	10	H4005S
Standard 15mm ISO Connector with Sideport; Tube Holder	5.0	10	H4006S
Low Dead Space 15mm ISO Connector with Sideport	2.5	10	H4001PS
Low Dead Space 15mm ISO Connector with Sideport	3.0	10	H4002PS
Low Dead Space 15mm ISO Connector with Sideport	3.5	10	H4003PS

Cuff inflator pressure gauge

- Controlled initial cuff inflation
- Intermittent pressure monitoring facility
- Instant visual confirmation of intra-cuff pressure
- Pressure adjustment is a simple operation. There is no need for disconnection or the introduction of a syringe into the system
- A connecting tube is supplied with the gauge for convenient positioning
- The gauge is portable and clips easily into a pocket



Ordering information

Description	Pack Qty	Product Code
Cuff Inflator and Pressure Gauge complete with Connecting Tube	1	100/568/000
Separate Connecting Tubes	10	100/569/000

4

Filtration & Humidification

All Smiths Medical HMEs provide efficient moisture recovery. They exhibit low resistance to flow and high moisture output which helps to minimise the loss of heat and moisture in ventilated or spontaneously breathing patients. Filters are available for use with mechanical ventilators, anaesthesia machines and open flow systems. Smiths Medical filters offer bacterial efficiency ratings up to > 99.99999%.* HMEs and filters have ISO standard tapered ends to assure a consistent leak-free seal.

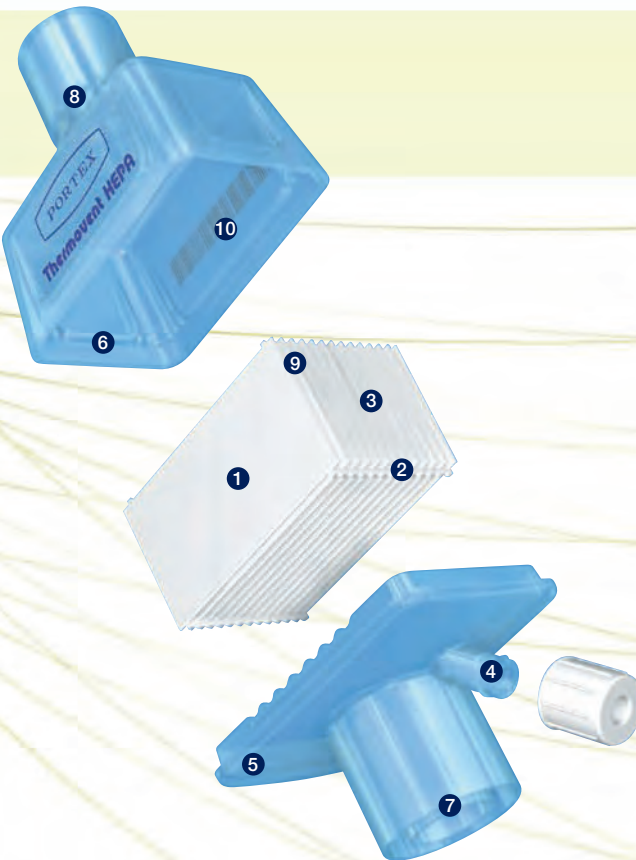
* CAMR, Porton Down, Test Report 444/98 Part 2 Thermovent HEPA

Thermovent® HEPA Filter

Thermovent HEPA is a hydrophobic bacterial and viral filter providing a highly effective barrier to both liquid and airborne micro-organisms while presenting minimal resistance to gas flow. They have been independently tested and shown to meet the proposed European Standard for viral and bacterial penetration both before and after 24 hours use.

Thermovent HEPA is 100% tested for filtration performance, resistance to flow and housing integrity during manufacture and supplied individually packed and sterile for single patient use.

Thermovent HEPA provides low deadspace filtration with heat and moisture exchange properties.



- Hydrophobic filter medium provides protection against liquid and airborne contamination
- Patented even-pleated filter medium allows maximum filtration efficiency with minimal resistance to flow
- Deep pleats ensure consistent gas flow during prolonged clinical use
- Gas sampling port, centrally positioned to ensure accuracy of readings
- Ergonomical design / smooth edges to aid patient comfort
- Transparent housing allows visual confirmation of performance
- 15mm/22mm conical connectors to ISO standards
- Anti-disconnect ring (as required by ISO 5356)
- Total encapsulation of all cut edges to avoid fibre shredding
- Bar code unique to each individual product to allow full traceability during manufacture, testing and use

Ordering information

Description	Pack Qty	Product Code
Thermovent HEPA	50	100/585/000

Thermovent® T HME

A Heat & Moisture Exchanger which captures heat and moisture on expiration and returns it to the patient on inspiration. It is suitable for spontaneously breathing patients with a tracheostomy tube.



- Low profile design. Ensures maximum comfort and minimal protrusion
- High performance, double paper element. An efficient heat and moisture exchanger to warm and humidify inspired air, reducing the risk of tube blockage from encrustations, with minimal resistance to flow
- Lightweight. Minimises the drag on the tracheostomy tube

Ordering information

Description	Pack Qty	Product Code
Thermovent T	50	100/570/015

Thermovent® O₂ -

Oxygen Delivery Aid for Thermovent® T HME

A specifically designed oxygen delivery aid for Thermovent T, provides the easiest and most comfortable way of supplying oxygen enriched humidified air.

- Clips easily onto the Thermovent T
- Supplied with 150cm connecting tube and coned mount for immediate connection to the oxygen source
- Balanced oxygen consumption is assured because of an even distribution of gas flow to both sides of the Thermovent T
- The light weight and small bulk of the product ensures maximum patient comfort



Ordering information

Description	Pack Qty	Product Code
Thermovent O ₂	10	100/575/010

Thermovent® 600 and Thermovent® 1200 Heat and Moisture Exchanging Filters

- High efficiency HME paper elements. Recovers approximately 75% of the energy and moisture that would otherwise be lost through respiration
- Low resistance to flow. Minimises pressure-build and reduces the work of breathing for weaning off the ventilator
- Small dead space. Suitable for both ventilated and spontaneously breathing patients
- Full compatibility with breathing systems or masks
- Thermovent 600 suitable for anaesthetised or ventilated patients who have a tidal volume of less than 600ml
- Thermovent 1200 suitable for anaesthetised or ventilated patients who have a tidal volume of less than 1200ml



Ordering information

Description	Pack Qty	Product Code
Thermovent 600 Sterile	10	100/580/015
Thermovent 1200 Sterile	10	100/582/000

Heat and Moisture Exchangers

Heat and Moisture Exchangers exhibit low resistance to flow and high moisture output in ventilated or spontaneously breathing patients. Smiths Medical offers a wide variety of products to include filters, breathing filters, filtered and non-filtered HME with or without a flex tube.

- High moisture retention and output to retain ciliary function
- Minimal Dead-Space. Can be used for a wide variety of tidal volumes
- Electrostatic Filtration. Affording protection to patients, staff and equipment
- Available with a flex tube for easier connection to endotracheal tube
- Available with gas sampling port



Ordering information

Description	Pack Qty	Product Code
HME	40	002840
HME with Flex Tube	20	002841
HEPA Filtered HME	20	002895
HEPA Filter	20	002890

5 Anaesthetic Breathing Systems and Accessories

Smiths Medical anaesthesia breathing systems offer the highest quality every time, designed with the clinician's needs and patient's comfort in mind. Smiths Medical accessories, including the catheter mount, SodaSorb® CO₂ absorbent and single-use face masks are also manufactured to the highest safety standards, making the route to patient recovery as smooth as possible.

Breathing Circuits

Smiths Medical are recognised as leaders in the supply of high quality, disposable Airway Management products, offering a complete system from patient to machine. Smiths Medical manufacture a wide variety of breathing circuits, all made with the same meticulous attention to detail, quality and precision to satisfy the majority of clinical needs.

For further information on breathing circuits, please contact your local Smiths Medical Specialist or Distributor.



Catheter Mount

- Acts as an adaptor between the breathing attachment and the tracheal or tracheostomy tube
- Reduces the transmission of movements from the breathing system to the tracheal/tracheostomy tube, thus reducing patient trauma
- Product transparency allows identification of blockages or fluid accumulation within the device
- Low deadspace, reduces rebreathing
- Available with 15mm Double Swivel Connector and Gas Sampling Elbow

Ordering information

Description	Pack Qty	Product Code
C.M. without Double Swivel Connector	20	100/590/000
C.M. with Double Swivel Connector	10	100/594/000
Catheter Mount	50	002837
C.M. with Gas Sampling Elbow	50	002838



Sodasorb® CO₂ Absorbent

Medical-grade SODASORB® (Soda Lime USP-NF) is the original CO₂ absorbent with a long tradition of quality and learned expertise. For more than eighty years, SODASORB® has consistently provided high quality performance and patient safety without compromise.

SODASORB® is specially designed and engineered for medical application in anaesthesia circuits/systems and respiratory therapy equipment.

- Excellent CO₂ absorption performance
- Optimal resistance to dusting
- High contrast colour change when absorbent capacity is exhausted - white to violet and pink to white both available
- Low resistance to gas flow
- Low Compound A and CO generation
- Available in different packaging variants



Ordering information

Description	Pack Qty	Product Code
Pre-Pak® Canister Discs, White, 1.13kg	12	008870
Eco Bag Canister Disc Refill, White, 1kg	9	008810
5 Litre Plastic Bottle Canister Disc Refill, White, 4.5kg	5	008850
Canister-Pak Canister Disc Refill, White, 1.27kg	12	008860
18.9 Litre Pail Canister Disc Refill, White, 16.8kg	1	008880
Pre-Pak® Canister Discs Samples, White, 1.13kg	2	008871*
Pre-Pak® Canister Discs, Pink, 1.13kg	12	008873
Eco Bag Canister Disc Refill, Pink, 1kg	9	008811
5 Litre Plastic Bottle Canister Disc Refill, Pink, 4.5kg	5	008851
Pre-Pak® Canister Discs Samples, Pink, 1.13kg	2	008874*

* For sampling purposes only
 Keep Sodasorb® containers tightly sealed and in a dry environment and away from temperatures above 32°F.
 Avoid direct sunlight and other types of UV intense light exposure.

Face Masks

Smiths Medical offers a comprehensive selection of disposable single-use anaesthesia face masks.



- Malleable cone conforms to patient facial features
- Crystal clear cone allows the clinician to visually monitor patients
- Clear, preinflated, anatomically-shaped cushions for gas tight, low-pressure seals
- Specially designed thumb rest offers ease of use for the clinician
- Colour-coded hook rings on selected masks makes size selection quick and easy
- Wide selection of configurations from neonate to large adult

Ordering information

Premium Air Cushion			
Description	Hook Ring	Pack Qty	Product Code
Adult	Blue	30	5045
Small Adult	Yellow	30	5055
Child	Clear	30	5048
Toddler	Green	30	5070
Infant	None	30	5052
Neonatal	None	30	5071
Premium Plus Air Cushion with inflation valve			
Adult	Blue	30	5245
Small adult	Yellow	30	5255
Child	Clear	30	5248
Toddler	Green	30	5270

6 Suction Catheters

In order to maintain a clean, hygienic environment for every patient, suction catheters are an essential part of the clinician's tool kit. The Smiths Medical range of suction catheters is all designed and manufactured to our exacting standards.

Closed Suction

Steri-cath

A closed ventilation suction system which allows simple and safe maintenance of pressures during suctioning of the critically ill patient, while also reducing the risk of cross contamination. Available in single and dual lumen.



Single lumen

- The whole of the lumen diameter is available as a suction pathway. Ideal if an irrigation channel is not required. Available with catheter mount in pack.
- Tracheal or Tracheostomy lengths available

Dual lumen

- Ideal if saline instillation is indicated. The integral irrigation line delivers fluid from the tip for effective bronchial lavage.
- Tracheal or Tracheostomy lengths available

Ordering Information

Sizes	O.D. (mm)	Length (mm)	Pack Qty	Product Code
Single Lumen				
Tracheal Length 10F	3.3	570	20	6104-10
Tracheal Length 12F	4.0	570	20	6104-12
Tracheal Length 14F	4.7	570	20	6104-14
Tracheal Length 16F	5.3	570	20	6104-16
Tracheostomy Length 14F	4.7	300	20	6109-14
Single Lumen with Catheter Mount				
Tracheal Length 10F	3.3	570	20	6104-10FE
Tracheal Length 12F	4.0	570	20	6104-12FE
Tracheal Length 14F	4.7	570	20	6104-14FE
Tracheal Length 16F	5.3	570	20	6104-16FE
Tracheostomy Length 14F	4.7	300	20	6109-14FE
Dual Lumen				
Tracheal Length 12F	4.0	570	20	6110-12
Tracheal Length 14F	4.7	570	20	6110-14
Tracheal Length 16F	5.3	570	20	6110-16
Tracheostomy Length 14F	4.7	300	20	6111-14
Closed Ventilation Suction Systems				
Single Lumen, Dual Swivel, Tracheal Length 10F	3.3	570	20	6152-10
Single Lumen, Dual Swivel, Tracheal Length 12F	4.0	570	20	6152-12
Single Lumen, Dual Swivel, Tracheal Length 14F	4.7	570	20	6152-14
Single Lumen, Dual Swivel, Tracheal Length 16F	5.3	570	20	6152-16
Single Lumen, Dual Swivel, Tracheostomy Length 12F	4.0	300	20	6153-12
Single Lumen, Dual Swivel, Tracheostomy Length 14F	4.7	300	20	6153-14
Dual Lumen, Dual Swivel, Tracheal Length 12F	4.0	570	20	6160-12
Dual Lumen, Dual Swivel, Tracheal Length 14F	4.7	570	20	6160-14
Dual Lumen, Dual Swivel, Tracheal Length 16F	5.3	570	20	6160-16
Dual Lumen, Dual Swivel, Tracheostomy Length 12F	4.0	300	20	6161-12
Dual Lumen, Dual Swivel, Tracheostomy Length 14F	4.7	300	20	6161-14

Closed Suction

Oral-Cath Oral Care System

The Oral Cath™ oral care device provides a convenient way to suction the mouth and nose without disconnecting the Steri-Cath system. The Oral-Cath device is designed with a 'Y' connection, allowing direct connection to a Steri-Cath device for a one suction canister set-up. It includes 10 disposable suction tips.



Ordering information

Description	Pack Qty	Product Code
Oral-Cath system	20	6105

Open Suction

Endobronchial Suction Catheters

The comprehensive range of endobronchial suction catheters with Terminal or Terminal and Lateral Eye offer easy access to the trachea and bronchi as well as quality, safety and economy in response to all suctioning requirements.



Ordering information

Endobronchial Suction Catheters					
Sizes (F)	O.D. (mm)	Length (mm)	Pack Qty	Terminal Eye Product Code	Terminal & 2 Lateral Eyes Product Code
4	1.3	380	50	100/360/040	-
5	1.7	380	50	100/360/050	-
6	2.0	460	50	100/360/060	100/361/060
8	2.7	460	50	100/360/080	100/361/080
10	3.3	460	50	100/360/100	100/361/100
12	4.0	610	50	100/360/120	100/361/120
14	4.7	610	50	100/360/140	100/361/140
16	5.3	610	50	100/360/160	100/361/160
18	6.0	610	50	100/360/180	100/361/180

Open Suction

Suction Catheters with Control Valve

- Suction Catheters with Control Valve are available straight or angled for positive control of suction pressure
- The terminal and 2 lateral eyes reduce the risk of blockage and traumatic tissue-grab



Ordering information

Suction Catheters with Control Valve					
Sizes (F)	O.D. (mm)	Length (mm)	Pack Qty	Straight Product Code	Angled Product Code
5	1.7	355	50	100/375/050	-
6	2.0	355	50	100/375/060	100/376/060
8	2.7	420	50	100/375/080	100/376/080
10	3.3	455	50	100/375/100	100/376/100
12	4.0	515	50	100/375/120	100/376/120
14	4.7	515	50	100/375/140	100/376/140
16	5.3	515	50	100/375/160	100/376/160
18	6.0	515	50	100/375/180	-

Neonatal Graduated Cathmark Suction Catheters

- For safer neonatal suctioning, these catheters come with a choice of male or female connectors
- The 2 lateral eyes placed close to the open end reduce the possibility of hypoxia



Ordering information

Suction Catheters with Control Valve				
Sizes (F)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
6	2.0	39	50	910/630/756
8	2.7	39	50	910/630/758

7 Respiratory Care

Smiths Medical provide a range of products to support the functions and maintain the effectiveness of the respiratory tract

Respiratory Care

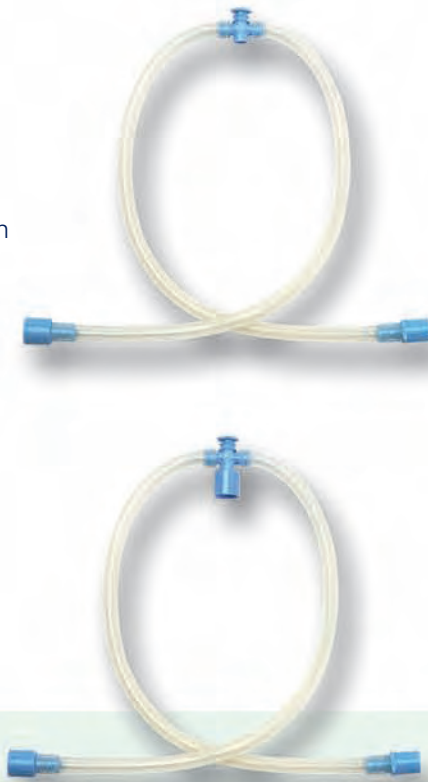
Ventilation/Breathing System, Infant

This ventilation/breathing system is simple and safe to use with unconscious or active conscious infants ensuring atraumatic fixation of the nasotracheal tube. The system comes complete and assembled with Portexsil tubing (800/500/size)

- 8.5mm or 15mm cross piece with suction port for connection to nasotracheal or tracheostomy tube
- 22mm humidification adaptor for direct connection to 22mm humidification tubing
- 15mm nipple adaptors for connection to paediatric mechanical ventilators
- 15mm non-occluding cage/gas bag mount

Ordering information

	Pack Qty	Product Code
Ventilation/Breathing System, Infant 8.5mm	10	100/268/000
Ventilation/Breathing System, Infant 15mm	10	100/259/000



Oxygen Set, Nasal

A convenient alternative to an oxygen mask for all respiratory and intensive therapy requirements.

- Leaves the patient's mouth free for nutritional and communication purposes
- Manufactured from soft, lightweight green PVC
- Fully adjustable support harness and nasal tips to provide maximum patient comfort and efficiency
- The 150cm of supply tube has a coned connector, avoiding the need for extension lines

Ordering information

	Pack Qty	Product Code
Oxygen set, nasal	10	100/285/100



Respiratory Care

Oxygen Catheter, Nasal

This catheter is for the administration of oxygen via the nasopharyngeal route.

- Manufactured from soft, green PVC to minimise trauma to delicate mucosal tissues
- An open end and multiple lateral eyes for even oxygen dispersion and prevention of jet effect
- Fitted with a tubing adaptor for easy connection to the oxygen source

Ordering information

	Pack Qty	Product Code
Oxygen catheter, nasal	10	100/280/130



Respiratory Therapy Masks

- Vinyl products for oxygen and aerosol administration
- Designed for anatomical compatibility
- Clear soft vinyl allows unobstructed view of patient and provides for better patient comfort.

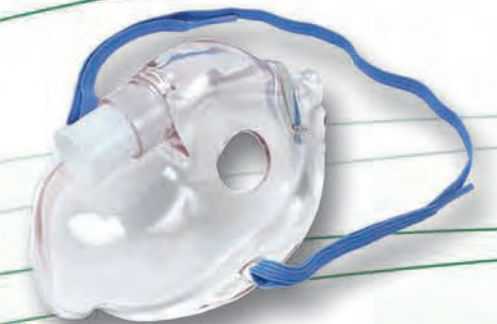
Ordering information

Respiratory Therapy Masks - Oxygen Masks

Description	Concentration	Oxygen Tubing	Pack Qty	Product Code
Adult, Under the Chin Style	Medium	7' (2.13m)	50	001421
Paediatric, Under the Chin Style	Medium	7' (2.13m)	50	001471

Respiratory Therapy Masks - Aerosol Masks

Description	Pack Qty	Product Code
Aerosol Mask, Vinyl, Adult	50	001426
Aerosol Mask, Vinyl, Paediatric	50	001476
Venturi Aerosol Mask, Vinyl, 24-50% Adjustable Entrainment, Adult	50	002610
Venturi Aerosol Mask, Vinyl, 24-50% Adjustable Entrainment, Paediatric	25	002620



Medication Nebuliser

Disposable medication nebulisers feature fine misting, spill-proof design and consistently therapeutic nebulisation.

- Angled medication cup for more efficient drug delivery
- Unique design of Baffle creates consistent particles of optimal therapeutic size to ensure quick and efficient delivery of medication
- "Fits-All" oxygen tubing connections eliminate the need for additional adaptors

Ordering information

Description	Product Code
Mini-Neb Nebuliser	002220
Mini-Neb Nebuliser Kit with tubing and Paediatric Aerosol Mask	002222
Mini-Neb Nebuliser Kit with tubing and Adult Aerosol Mask	002223



Respiratory Care

Twin Nasal Cannula, C.P.A.P.

The Twin Nasal Cannula offers a simple, efficient method for administering continuous positive airway pressure to infants suffering from Respiratory Distress Syndrome

- Smooth bevelled cannula tips assist trauma-free intubation
- Kink-resistant supporting cross-piece provides a safe method of securing the cannulae and maintaining them in correct position
- Flexible and lightweight construction minimises drag
- Easy access to patient maintained



Ordering information

Size ID (mm)	Length Nasal Tips (mm)	Pack Qty	Product Code
2.5	16.0	10	100/295/010
3.0	19.0	10	100/295/020
2.5	48.0	10	100/295/030
3.0	50.0	10	100/295/040

Humidifiers, Nebulisers, Incentive Spirometers and IPPB Manifolds

- Humidifiers and Nebulisers with Dial Design. Accurate FiO2 ranges from 35% to 100%. Large, easy to read numbers
- Unique design of Baffle creates consistent particles of optimal therapeutic size
- Incentive Spirometers with wide range of flow and dial settings. From 120cc/sec to 1600cc/sec
- IPPB Manifolds. Swivelling Exhalation Caps. Wrapped Mouthpieces and Anti-Spill Plates



Ordering information

Description	Pack Qty	Product Code
Incentive Spirometers		
Incentive Spirometers	20	002000
IPPB Manifolds		
Universal IPPB Manifold with Baffle for Faster nebulisation rate	25	002218A
Single Use Mouthpieces		
Mouthpiece, Soft Flange, 22mm OD	50	002550

8

Respiratory Care Accessories

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

Accessories

Catheter Mount Adaptor - Female, Reusable, 15mm

This adaptor provides a simple and secure connection between the swivel connector and catheter mount tubing.

- Manufactured from durable lightweight polypropylene
- Suitable for a maximum 11mm ID catheter mount



Ordering information

Description	Pack Qty	Product Code
Catheter Mount Adaptor - Female, Reusable, 15mm	10	100/251/001

Connector - Tracheal Tube Set, 15mm, Reusable

Providing a versatile means of connecting tracheal tubes to anaesthetic and ventilator circuits, the set includes all sizes of connector from 2.5mm to 11.0mm in steps of 0.5mm.

The set consists of:

18 tracheal connectors, 1 swivel connector, 1 15mm/15mm connector,
1 15mm female catheter mount adaptor

- Manufactured from lightweight durable plastics
- Swivel connector rotates through 360° and allows direct access to the trachea for suctioning
- 15mm female catheter mount adaptor ensures that the swivel connector fits all sizes of anaesthetic catheter mount tubing



Ordering information

Description	Pack Qty	Product Code
Tracheal Tube Set	1	100/253/000

Connector - Swivel, 15mm, Reusable

- Ideal for single or multiple use applications
- Full rotation through 360° at the patient end allows the respiratory circuit to assume a natural position
- Easy access to suction port
- 15mm male and female fittings



Ordering information

Description	Pack Qty	Product Code
Connector - Swivel	10	100/250/001

Accessories

Tracheal Tube Adaptor, Reusable

This connector provides a secure method of connecting tracheal tubes to anaesthetic and ventilation circuits

- 100/252/020-045 manufactured from lightweight polyester
- 100/252/050-150 manufactured from lightweight polypropylene
- Comprehensive size range



Ordering information

Size (mm)	Pack Qty	Product Code
2.0	10	100/252/020
2.5	10	100/252/025
3.0	10	100/252/030
3.5	10	100/252/035
4.0	10	100/252/040
4.5	10	100/252/045
5.0	10	100/252/050
5.5	10	100/252/055
6.0	10	100/252/060
6.5	10	100/252/065
7.0	10	100/252/070
7.5	10	100/252/075
8.0	10	100/252/080
8.5	10	100/252/085
9.0	10	100/252/090
9.5	10	100/252/095
10.0	10	100/252/100
10.5	10	100/252/105
11.0	10	100/252/110
15.0	10	100/252/150

Carden Swivel Connector - Bivona

- Individually packed
- Complete with Fibreoptic Bronchoscope/Suction port with cap
- 15mm swivel connector



Ordering information

Product Code
CARSWL

Connector - Fibreoptic Bronchoscope Swivel, 15mm, Reusable

This connector enables brochoscopy to be performed through an established tracheal airway without loss of gases in the ventilator circuit.

- Suction port capped by a PVC cover with a plugged port, which forms a wiper seal around a fibreoptic bronchoscope
- The diameter of the bronchoscope port is 5.0mm which is suitable for Olympus type instruments



Ordering information

Description	Pack Qty	Product Code
Connector - Fibreoptic Bronchoscope Swivel	10	100/257/000

Accessories

Connector - Right Angled, 15mm, Reusable

This connector provides a secure coupling for the 15mm termination of tracheal connectors to catheter mount tubing.

- Compact design
- Lightweight
- Minimal dead space, particularly suitable for paediatric use



Ordering information

Description	Pack Qty	Product Code
Connector - Right angled	10	100/254/001

Tracheal Tube Connector, (Cobbs Type), Reusable

This lightweight translucent connector provides a direct method of incorporating tracheal tubes into anaesthetic and ventilator circuits.

- Right angle design ensures that the connections are diverted away from the patient and operative area
- The design of the connector minimises dead space
- Convenient suction port
- Available in 4 sizes



Ordering information

Description	Pack Qty	Product Code
5.0-6.0mm	10	100/240/050
6.5-8.0mm	10	100/240/065
8.5-10.0mm	10	100/240/085
10.5-12.0mm	10	100/240/105

Connector - Double Swivel

This double swivel connector combines the convenience and economy of a single-use item with a lightweight versatile design.

- Full rotation through 360° in two planes allowing the respiratory circuit to assume a natural angle
- Easy access suction port permits safe suctioning without disconnection, a positive aid to patient comfort
- Precise 15mm male and female fittings together with anti-disconnect lugs ensure a positive and secure connection



Ordering information

Description	Pack Qty	Product Code
Connector - Double Swivel	10	100/255/150

Accessories

Connector - Paediatric, 8.5mm

"Mini-link" connectors provide a secure method of connecting paediatric tracheal tubes to anaesthetic and ventilation circuits.

- Lightweight- reduces erosion of the nares caused by the weight of 15mm connectors
- Low dead space to minimise rebreathing
- Flange has two flat edges - ideal for nasal intubations avoiding unnecessary tissue contact
- Has a 'push twist' action for safe connection



Ordering information

Size (mm)	Pack Qty	Product Code
2.0	10	100/262/020
2.5	10	100/262/025
3.0	10	100/262/030
3.5	10	100/262/035
4.0	10	100/262/040
4.5	10	100/262/045
5.0	10	100/262/050
5.5	10	100/262/055
6.0	10	100/262/060

Connector - Tracheostomy Tube, 8.5mm, G.O.S

This connector provides a simple way of connecting a G.O.S pattern tracheostomy tube to anaesthetic or ventilation circuits.

- Rounded end to ensure a good connection in the standard well of a G.O.S. (Great Ormond Street Hospital) tracheostomy tube
- Male 8.5mm taper to mate with a 8.5mm female cross piece on "Mini-link" ventilation breathing system
- Lightweight. The connector does not drag on the tracheostomy tube
- Low dead space enables the connector to fit comfortably under the infant's chin



Ordering information

Description	Pack Qty	Product Code
Connector - Tracheostomy Tube, 8.5mm, G.O.S.	10	100/263/085

Adaptor/Humidification, Non-Sterile

- The 15mm Female/22mm Male connector, may be used at the patient end of the 22mm humidification tubing
- The 15mm Male/22mm Male connector, interfaces with the machine end of the 22mm humidification tubing



Ordering information

Description	Product Code
15mm Female/22mm Male Connector	100/272/000
15mm Male/22mm Male Connector	100/273/000

Accessories

Connector - Angled, 8.5mm

An angled connector which provides a secure coupling between the 8.5mm "Mini-link" tracheal tube connectors and the 8.5mm "Mini-link" Ayre's 'T' Piece

- Connector designed for use in both oral and nasal intubation
- Angle of connector may be changed by reversing the suction port cap. This feature is essential for nasally intubated patients so that there will be no distortion to the nares or nasal passage



Ordering information

Description	Pack Qty	Product Code
Connector - Angled, 8.5mm	10	100/264/000

Suction Port Cap, Replacement - 8.5mm, White, 15mm, Blue

For use with angled connector

- Replacement port caps minimise the risk of contamination after tracheal suctioning
- Colour coded white or blue for ease of identification with 8.5mm and 15mm Infant Ventilation/Breathing Systems



Ordering information

Description	Pack Qty	Product Code
8.5mm Replacement Suction Port Cap (White)	10	100/269/085
15mm Replacement Suction Port Cap (Blue)	10	100/269/150

Catheter Mount Adaptor - 8.5mm

This adaptor provides a simple and secure connection between "Mini-link" paediatric angled connector and catheter mount tubing

- Low dead space to minimise rebreathing



Ordering information

Description	Pack Qty	Product Code
Catheter Mount Adaptor - 8.5mm	10	100/261/000

Accessories

Ayre's 'T' Piece, 8.5mm Adaptor (available with 15mm connection)

The simplicity and reliability of the Ayre's 'T' Piece makes it the most favoured solution to the problem of breathing systems for infants

- Lightweight connectors are compatible
- Low dead space reduces the effect of rebreathing
- 8.5mm female taper mates with 8.5mm male tracheal tube connector
- 'T' Piece is compatible with 15/22mm face mask adaptor to enable induction of anaesthesia with Mini-link 8.5mm Ayre's 'T' Piece
- Choice of ribbed termination to enable direct fit to reservoir tubing or 15mm termination to enable connection to existing reservoir tubing arrangement



Ordering information

Description	Pack Qty	Product Code
"Mini-link" 8.5mm Ayre's 'T' Piece	10	100/266/000
"Mini-link" 8.5mm Ayre's 'T' Piece with 15mm termination	10	100/266/015

Adaptor - 8.5mm Female/15mm Male

8.5mm female to 15mm male connector eliminates the risk of incompatibility between 8.5mm and 15mm systems.



Ordering information

Description	Pack Qty	Product Code
Adaptor - 8.5mm Female/15mm Male	10	100/265/000

Adaptor/Connector - Face mask, Co-Axial, 15mm

- Ideal for single-use applications
- External taper allows it to fit into a face mask
- 15mm female taper allows connections straight to 15mm tracheal tube connector
- 15mm male taper fits 15mm Ayre's 'T' Piece
- Internal taper is compatible with 8.5mm Ayre's 'T' Piece



Ordering information

Description	Pack Qty	Product Code
Adaptor/Connector - Face mask, Co-Axial, 15mm	10	100/274/000

Accessories

'Y' Piece Connector, 15mm

A modified Ayre's 'T' Piece with a flow tube at an acute angle to reduce bulkiness of the system.

- Design minimises the risk of disconnection
- Lightweight and therefore more suitable for use with infants

Ordering information

Description	Pack Qty	Product Code
'Y' Piece Connector, 15mm	10	100/276/000



Gas Bag Mount, Non-Occluding Cage, 15mm

A protective cage and bag mount which may be attached at the end of a reservoir limb using 15mm connectors

- Prevents accidental occlusion of the reservoir limbs

Ordering information

Description	Pack Qty	Product Code
Gas bag mount, non-occluding cage, 15mm	10	100/277/000



RSP® Endotracheal Tube Connector, with Sideport

- ISO Connectors - conform to ASTM standards, low dead space connector decreases CO₂ retention

Ordering information

Description	Pack Qty	Size	Product Code
Endotracheal Tube Connectors with Sideport			
15mm ISO Connector with Sideport	50	2.5	10025-05S
15mm ISO Connector with Sideport	50	3.0	10030-05S
15mm ISO Connector with Sideport	50	3.5	10035-05S
15mm ISO Connector with Sideport	50	4.0	10040-05S
15mm ISO Connector with Sideport	50	4.5	10045-05S
15mm ISO Connector with Sideport	50	5.0	10050-05S
15mm ISO Connector with Sideport	50	5.5	10055-05S
15mm ISO Connector with Sideport	50	6.0	10060-05S
15mm ISO Connector with Sideport	50	6.5	10065-05S
15mm ISO Connector with Sideport	50	7.0	10070-05S
15mm ISO Connector with Sideport	50	7.5	10075-05S
15mm ISO Connector with Sideport	50	8.0	10080-05S
15mm ISO Connector with Sideport	50	8.5	10085-05S
15mm ISO Connector with Sideport	50	9.0	10090-05S
15mm ISO Connector with Sideport	50	9.5	10095-05S
15mm ISO Connector with Sideport	50	10.0	10010-05S
Low Dead Space Endotracheal Tube Connectors with Sideport			
15mm ISO Connector with Sideport	50	2.5	1002



9

Emergency Medicine

Smiths Medical has developed a variety of resuscitation products that enable provision of effective pulmonary resuscitation quickly and safely. Throughout the range of these disposable devices, we clearly offer the widest range of options for pulmonary resuscitation, all of which offer maximum ease of use, durability and performance.

Smiths Medical 1st Response™ Manual Resuscitators

Including the NEW Smiths Medical CO₂ Clip™ - Colourmetric Carbon Dioxide Detection System

Practical, Effective, Flexible Resuscitation From Smiths Medical

Smiths Medical 1st Response™ manual resuscitation bags are single use, reducing the risk of patient to patient cross-infection, while allowing effective monitoring through all phases of resuscitation.

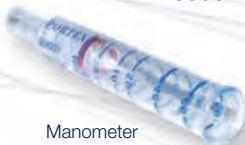
Practical

- New wider SureGrip™ textured panels, enhance tactile feel and improve security of grip when used with wet hands.
- Complete, single use kits minimise the risk of cross-infection and reduces the problems related to lost components, thereby saving valuable staff time.
- Transparent construction allows clear view of valve function and easy visualisation of any patient secretions which might cause occlusion.
- Sensitive, one way, non-rebreathing duckbill valve reduces secretions entering fresh gas supply.



Effective

- New, low deadspace horizontally oriented patient valve assembly allows clear view of valve function and easy identification of contamination without obscuring the view of the patient.
- Integral 360° swivel connector permits optimal bag positioning and reduces airway torque.
- New 8501 PEEP valve and exhalation port filter connects directly to the enlarged 30mm exhaust port. PEEP valve adjusts from 5-20cm H₂O.
- Disposable Manometer lightweight and easy to use. Two scales measuring normal PEEP and peak inspiratory pressure. Convenience, reliable and accurate.



Flexible

- Choice of oxygen reservoirs with improved internal oxygen line attachment.
- 40" Flexible tubing for adult and paediatric versions.
- 18" Flexible tubing with infant version.
- Clear bag reservoir.
- Expandable tube reservoir.
- Available as a range of kits and configurations to suit your particular needs.

Paediatric & Infant resuscitators

- Low deadspace design (<7mL) for reduced volume rebreathing.
- Preset pressure limiting valve, set to open at 40cmH₂O.
- Manometer port with tethered dust caps to allow for pressure limiting valve override.
- Large paediatric resuscitators now available



Adult Resuscitators

- New collapsible volume bag and self-sealing packaging make 1st Response™ easier to store and access while minimising the risk of damage.
- New compact box pack option, ideal when space is at a premium, for example in emergency vehicles and resuscitation trolleys etc.
- New adult face mask has improved shape and feel.
- A rigid connector eliminates the need for a support collar, and a clear cone and seal allows the best view of the patient.



Smiths Medical CO₂ Clip™

- Smiths Medical CO₂ Clip™ Colourmetric Carbon Dioxide Detection System. The fast responding sensor that detects the inspiratory and expiratory CO₂ concentration breath - by - breath.



Product Ordering information

Smiths Medical CO₂ Clip™ Ordering Information

Ref Code	Description	Units Per Case
8530C	Individually packaged CO ₂ detectors with attached airway adapter	12
8530C-25	Individually packaged CO ₂ detectors with attached airway adapter	25

Smiths Medical CO₂ Clip™ with 1st Response™ Manual Resuscitators Ordering Information

Ref Code	Description	Units Per Case
Adult		
8500CE	Adult resuscitator with tethered dust cap, reservoir bag, adult mask, CO ₂ Clip™	12
8503CE	Adult resuscitator with tethered dust cap, 40" (101 cm) flexible tubing reservoir, adult mask, CO ₂ Clip™	12
Paediatric		
8520CBE	Paediatric resuscitator with tethered dust cap, reservoir bag, child mask, CO ₂ Clip™	9
8520CE	Paediatric resuscitator with tethered dust cap, 40" (101 cm) flexible tubing reservoir, child mask, CO ₂ Clip™	9
Infant		
8528CMBE	Infant resuscitator with tethered dust cap, reservoir bag, infant and neonate mask, CO ₂ Clip™	9
8528CME	Infant resuscitator with tethered dust cap, 18" (46 cm) flexible tubing reservoir, infant and neonate mask, CO ₂ Clip™	9
8501E	PEEP Valve (range 5 - 20 cm H2O)	12
8518E	30 mm Exhalation Port Filter	40
008201	Disposable Manometer	20

Range of Manual Resuscitators with CO² Clip available Q4 2005

Hyperinflation Systems

The Smiths Medical Hyperinflation System represents quality, safety and convenience.

Available with our unique, user-friendly disposable manometer, Smiths Medical hyperinflation systems provide a visual indication of the patient's airway pressure during ventilation.



Thumb Control Bleed Valve System

- Easy to use
- Positioned near ventilation bag allowing one-handed adjustment

Dual Swivel Elbow

- Reduces airway torque
- Improves repositioning when using a disposable mask

Multiple Sizes and Configurations

- 0.5ltr and 1.0ltr non-latex bags
- 0.5ltr, 1.0ltr, 2.0ltr and 3.0ltr latex bags
- Available with disposable manometer line, or 40cm/H₂O pressure limiting valve

Disposable Manometer

- Lightweight and easy to use
- Two scales measuring normal PEEP and peak inspiratory pressure
- Convenient, reliable and accurate

Ordering information

Product Description	Pack Qty	Product Code
0.5L Hyperinflation bag, standard elbow manometer	20	008430M
0.5L Hyperinflation bag, pressure limiting valve elbow manometer	20	008430VM
0.5L Hyperinflation bag, dual swivel elbow manometer, infant mask	20	008432DM
1L Hyperinflation bag, dual swivel elbow manometer	20	008435DM
Disposable Manometer	20	008201

Infants' Resuscitation Tube Set

The infants' resuscitation tube set is specially designed and ideally suited for emergency resuscitation of the new born.

- Set permits intermittent positive pressure ventilation and suctioning without disconnecting from the circuit
- Sterile pack contains a Cole's neonatal tube with attached 'T' piece and a suction catheter complete with female mount
- Choice of 4 sizes



Ordering information

Size ID (mm)	Suction Catheter (F)	Pack Qty	Product Code
1.5	4	10	100/420/150
2.0	5	10	100/420/200
2.5	5	10	100/420/250
3.0	5	10	100/420/300

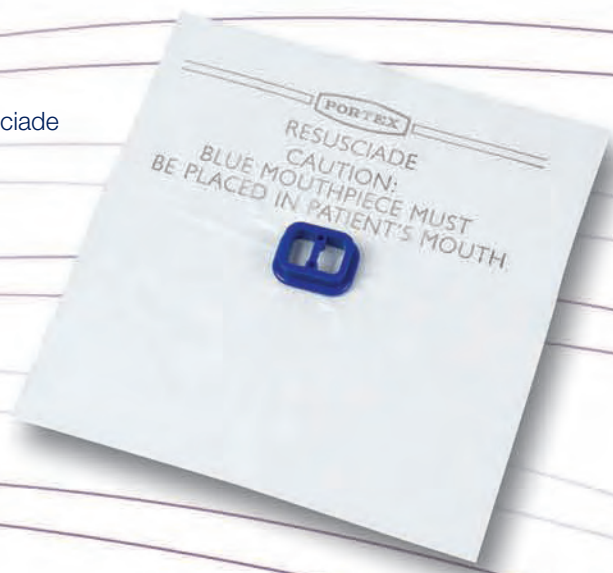
Resusciade

This potential life-saver should be an essential component in every first-aid kit for administration of mouth-to-mouth resuscitation following cardiac arrest, accidents in the home, factory or during water sports etc.

- Combination of PVC sheet, one-way valve and bite block avoids potentially unpleasant or dangerous direct contact, whilst helping maintain airway patency
- Compact pocket-size device
- Simple instructions for use are supplied with every Resusciade so that the emergency technique can be applied rapidly

Ordering information

	Pack Qty	Product Code
Resusciade	10	100/341/010



Resuscitation Tube

- The design prevents tongue obstruction
- Comprehensive size combinations to suit both patient and first-aider
- Integral moulded nylon bite block eliminates tube occlusion caused by teeth clamp down



Ordering information

Size	Length (cm)	Pack Qty	Product Code
000/00	3.5/5.0	1	100/340/000*
2/3	9.0/10.0	1	100/340/230
2/4	9.0/11.0	1	100/340/240
3/4	10.0/11.0	1	100/340/340

NB: The mouth-to-mouth resuscitation tube should only be used by those fully trained in its correct application and method of insertion

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

Custom Kitting

- benefits for the user

Individual Kits

Custom kits ensure you receive exactly the right components for each individual, with no extras to assemble and nothing wasted.

Time Saving

All the items necessary, from set up to procedural application, are present in one package.

Single Handling

Items are only handled once, reducing the risk of infection.

- benefits for the buyer

Simple Ordering

A single order for each pack - contains all components.

Reduced Wastage

The exact number of components is provided according to individual preference.

Reduced Stockholding

Packs held by customary distributor according to forecast demand.



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002000	51	100/132	19	100/269	57	15W	23
002218A	51	100/133	18	100/274	58	197	26
002550	51	100/134	20	100/276	59	198	26
002610	50	100/136	18	100/277	59	002837	41
002620	50	100/141	13	100/280	50	002838	41
002840	39	100/162	10	100/285	49	5045	43
002841	39	100/166	10	100/295	51	5048	43
002890	39	100/174	11	100/303	30	5052	43
002895	39	100/178	11	100/320	30	5055	43
008027MP	62	100/179	11	100/340	65	5070	43
008120	62	100/190	27	100/341	64	5071	43
008201	63	100/196	29	100/360	46	5245	43
008430M	63	100/199	9	100/361	46	5248	43
008430VM	63	100/210	31	100/375	47	5255	43
008432DM	63	100/220	7,8	100/376	47	5270	43
008435DM	63	100/240	55	100/420	64	6104	45
0088	42	100/250	53	100/430	15	6105	46
100/105	14	100/251	53	100/431	15	6109	45
100/107	21	100/252	54	100/570	38	6110	45
100/108	21	100/253	53	100/575	38	6111	45
100/109	21	100/254	55	100/580	39	6152	45
100/110	21	100/255	55	100/582	39	6153	45
100/111	12	100/257	54	100/585	37	6160	45
100/112	15	100/259	49	100/590	41	6161	45
100/113	21	100/261	57	100/594	41	65W	27
100/120	33	100/262	56	100/603	33	7500	25
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