

# 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 distribuția 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:**

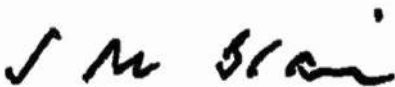
**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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.

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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**

Brightwake Limited  
Lowmoor Business Park  
Kirkby-in-Ashfield  
Nottinghamshire  
NG17 7JZ  
United Kingdom

**Manufacture**

GaleMed Corporation  
No. 87, Li-Gong 2nd Road  
Wu-Jia  
YILAN 268  
Taiwan

**Manufacture**

GE Medical  
Pollards Wood  
Nightingales Lane  
Chalfont Saint Giles  
HP8 4SP  
United Kingdom

**Manufacture**

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# EC Certificate - Full Quality Assurance System

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

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**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

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**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	<b>Manufacture</b>
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	<b>Manufacture</b>

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# EC Certificate - Full Quality Assurance System

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

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 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

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

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

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

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

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

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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 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

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

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





Certificat nr.: CE 661325

## Obiectul certificatului:

### Proiectarea, dezvoltarea si fabricatia produselor sterile:

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

### Proiectarea, dezvoltarea si fabricatia de produse nesterile:

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

Prima editie: **2017-06-28**Data: **2017-06-28**Data expirarii: **2022-06-27**

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Pagina 2 of 2

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

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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

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

**Fabricatie**

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

**Fabricatie**

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

**Fabricatie**

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# Certificat CE - Sistem Integral de Asigurare a Calitatii

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

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

### Subcontractant:

### Servicii prestate

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

**Fabricatie**

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

**Furnizor crucial**

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

**Fabricatie**

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# Certificat CE - Sistem Integral de Asigurare a Calitatii

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

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**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

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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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**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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**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

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**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

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**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

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**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Marea Britanie**

**Subcontractant:****Servicii prestate**

Sterigenics US, LLC  
344 Bonnie Circle  
Corona  
California  
92880  
USA

**Sterilizare cu raze gamma**

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

**Sterilizare cu raze gamma**

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

**Sterilizare ETO**

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# Certificat CE - Sistem Integral de Asigurare a Calitatii

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

## Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

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

### Subcontractant:

### Servicii prestate

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

**Sterilizare ETO**

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

**Fabricatie**

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

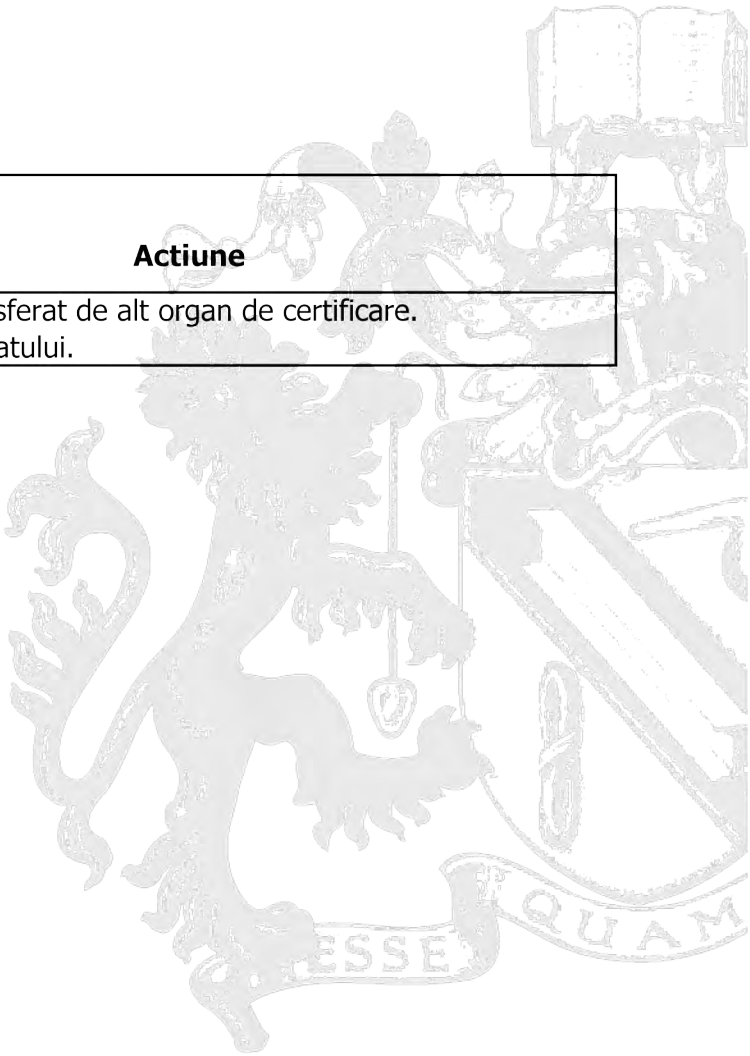
**Furnizor crucial**

...making excellence a habit.™

# 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:**

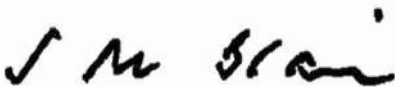
**Smiths Medical International Ltd.  
Boundary Road  
Hythe  
Kent  
CT21 6JL  
United Kingdom**

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

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

# Certificat CE de examinare a proiectului

Informatii suplimentare pentru CE 661326

Titular:

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

## Istoricul Certificatului

Data	Numar de referinta	Actiune
Curenta	10166350	Prima editie. Transferat de un alt organ de certificare.

Prima editie: 2017-06-28

Data: 2017-06-28

Data expirarii: 2022-06-27



# EC Certificate - Production Quality Assurance

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

**No.****CE 661328****Issued To:**

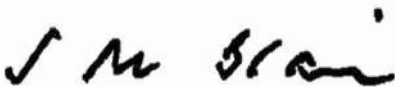
**Smiths Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**United Kingdom**

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	<b>Manufacture</b>
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	<b>Manufacture</b>

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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**

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Pagina 1 din 2

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

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

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





**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.

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

**Lista Principalilor Subantreprenori**

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

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

<b>Subantreprenor</b>	<b>Servicii furnizate</b>
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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**CT21 6JL**  
**Regatul Unit**

<b>Subantreprenor</b>	<b>Servicii furnizate</b>
Koo Medical Equipment (Shanghai) Co. Ltd. 100 Zhongde Road Dakun Industrial Park Songjiang, Shanghai 201614 China	Fabricare

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Pentair Filtration Solutions 1350 Hammond Road, St. Paul Minnesota 55110 SUA	Furnizor Principal
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Quadrant EPP Belgium N.V. Industriepark Noord Robert Tavernierlaan 2 Tielt 8700 Belgia	Fabricare
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**CT21 6JL**  
**Regatul Unit**

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

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**Kent**  
**CT21 6JL**  
**Regatul Unit**

<b>Subantreprenor</b>	<b>Servicii furnizate</b>
Smiths Medical ASD Inc. 10 Bowman Dr. Fabricare Keene, New Hampshire, 03431 SUA	

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Smiths Medical ASD Inc., 1265 Grey Fox Road, St. Paul, Minnesota 55112 SUA	Fabricare
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Smiths Medical ASD Inc., 201 West Queen St., Southington, Connecticut 06489 SUA	Fabricare
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**Kent**  
**CT21 6JL**  
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<b>Subantreprenor</b>	<b>Servicii furnizate</b>
Smiths Medical ASD Inc., 6250 Shier Rings Road, Dublin, Ohio 43016 SUA	Fabricare
Smiths Medical ASD Inc., 9124 Polk Lane, Suite 101 Olive Branch, Mississippi 38654 SUA	Distribuție
Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice Republica Cehă	Fabricare

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Data: **28-06-2017**  
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**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

<b>Subantreprenor</b>	<b>Servicii furnizate</b>
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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**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

<b>Subantreprenor</b>	<b>Servicii furnizate</b>
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
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Sterigenics UK Limited, Cotes Park Estate, Somercotes Alfreton, DE55 4NJ Regatul Unit	Sterilizare ETO
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Emis pentru: **Smith Medical International Ltd.**  
**Boundary Road**  
**Hythe**  
**Kent**  
**CT21 6JL**  
**Regatul Unit**

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

---

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

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

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**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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Pagina 1 din 1

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\*\*\*\*\*

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Traducător autorizat  
Nr. 2769/2015



# Certificate of Registration



# Intertek

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

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



061



*Brian Johnson*

*AMTAC Certification Services Limited, Milton Keynes, UK*

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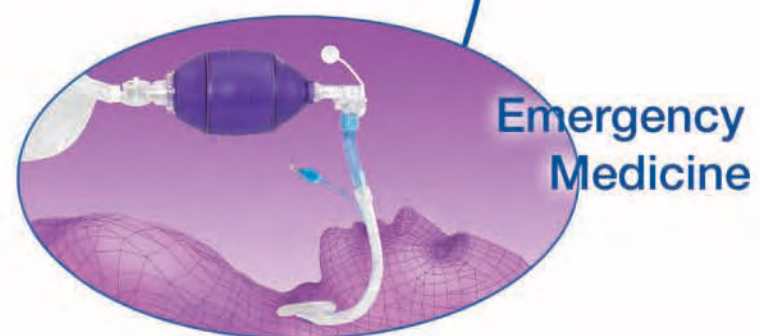
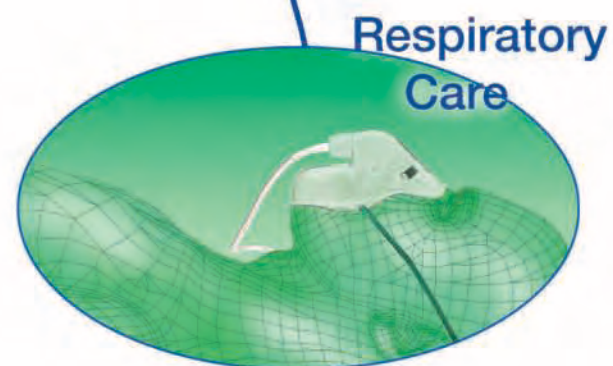
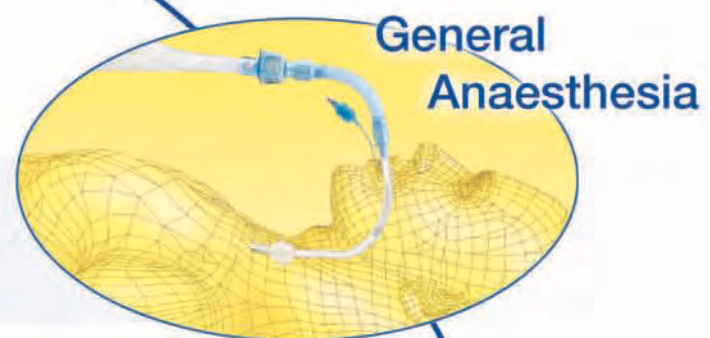
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MIRELA  
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12.09.2008  
AUTORIZAT

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## Smiths Medical



### UK Customer Services

Customers in the UK with queries on any product in this supplement should contact:

Tel: 01923 246434

Fax: 01923 231595

### International Customer Services

Customers outside the UK with queries on any product in this supplement should contact:

Tel: +44 (0) 1303 260551

Fax: +44 (0) 1303 236899

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

Additional information is available at [www.smiths-medical.com](http://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



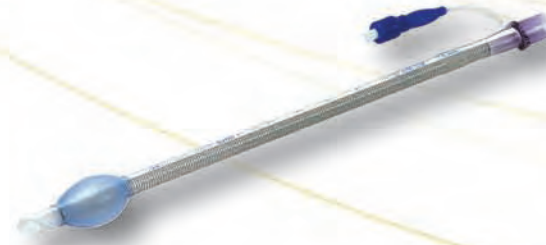
### Reinforced PVC\*



### Polyurethane



### Silicone



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

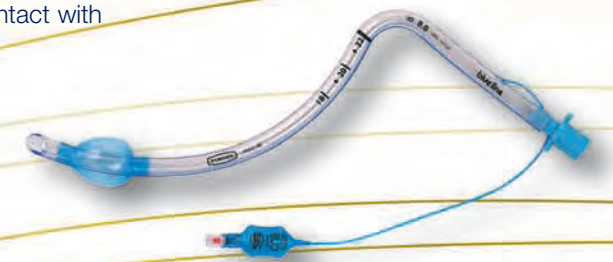
### Profile Soft Seal cuff

- 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 transmission<sup>1</sup>.

*"...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."*<sup>1</sup>

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<sup>2,3</sup>, 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

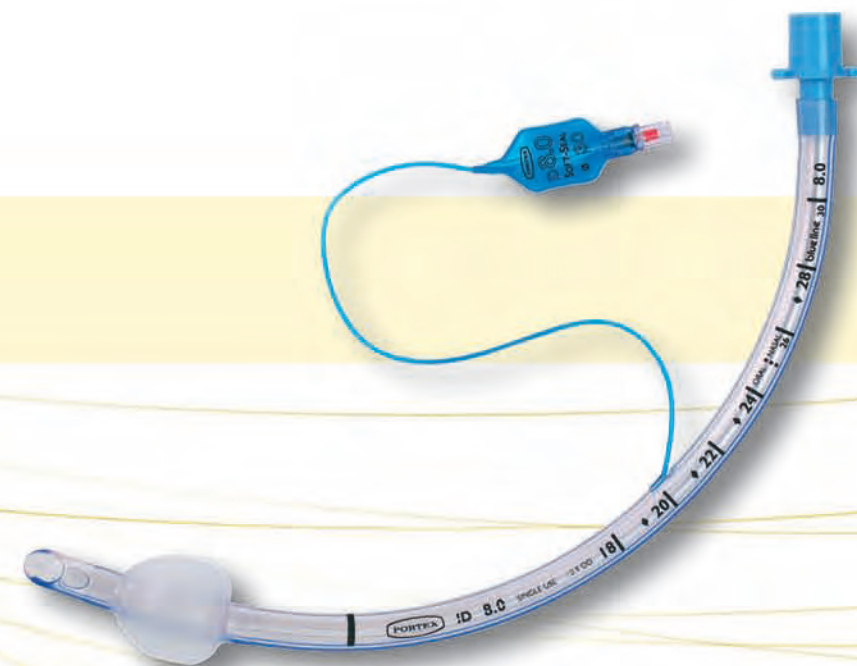
3 Bench test data on file



# 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*



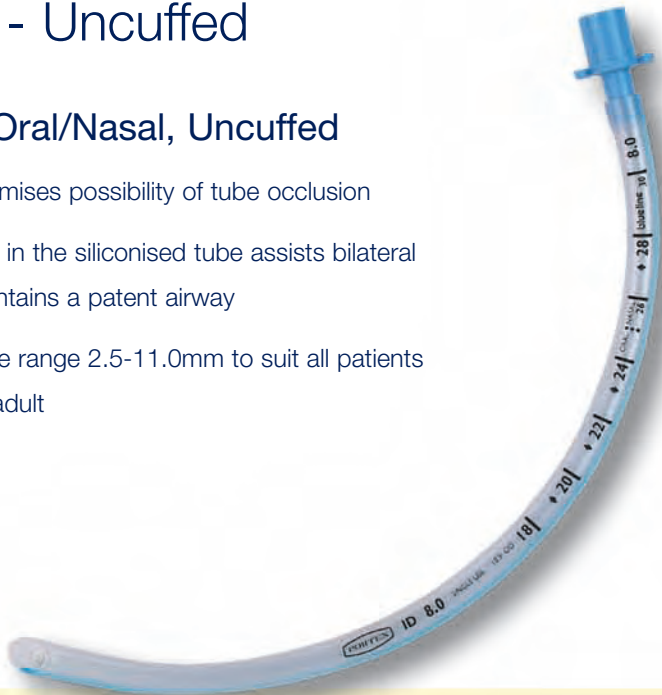
\* Please Note: These items are made to order only, please contact Customer Services with regard to lead time.



# 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

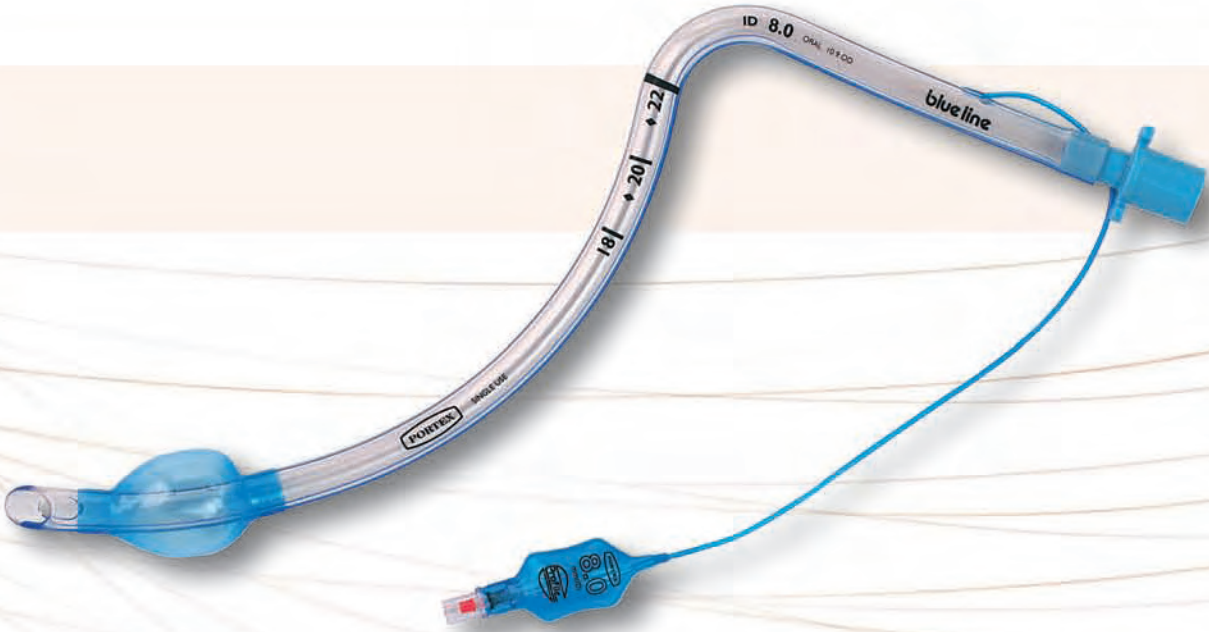
All Smiths Medical Intubation Specialist Tubes are manufactured to the highest quality standards, specifically for specialised clinical needs. Available cuffed and uncuffed, polar preformed, reinforced or in silicone to suit individual clinician's requirements.



# 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

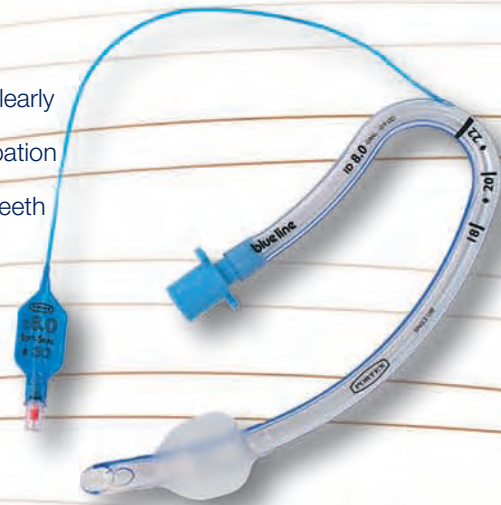


### Ordering information

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 <sup>1</sup>	Product Code <sup>2</sup>	Product Code <sup>3</sup>
2.5	4.0	14	10	-	-	35W025 <sup>B</sup>
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 <sup>A</sup>	25W060 <sup>A</sup>	35W060 <sup>A</sup>
6.5	9.4	28	10	20W065	25W065 <sup>A</sup>	35W065 <sup>A</sup>
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

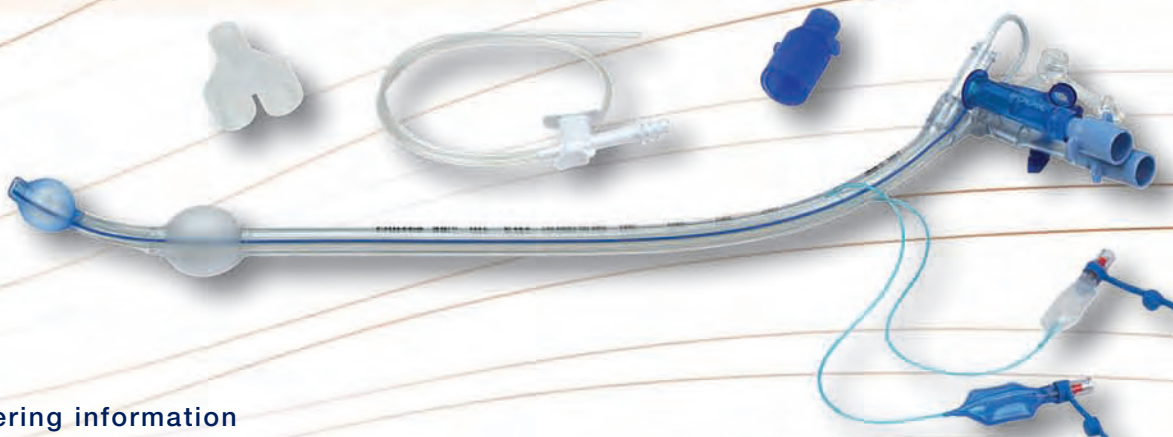
I.D. (mm)	O.D. (mm)	Length (cm)	Pack Qty	Product Code
6.0	8.7	29	10	750060
6.5	9.4	30	10	750065
7.0	10.0	31	10	750070
7.5	10.4	32	10	750075
8.0	11.0	33	10	750080
8.5	11.8	33	10	750085
9.0	12.3	33	10	750090
9.5	13.3	33	10	750095



# 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 CO<sub>2</sub> 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
<b>Endotracheal Tube Connectors with Sideport</b>			
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
<b>Extra Long Stylets</b>				
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.

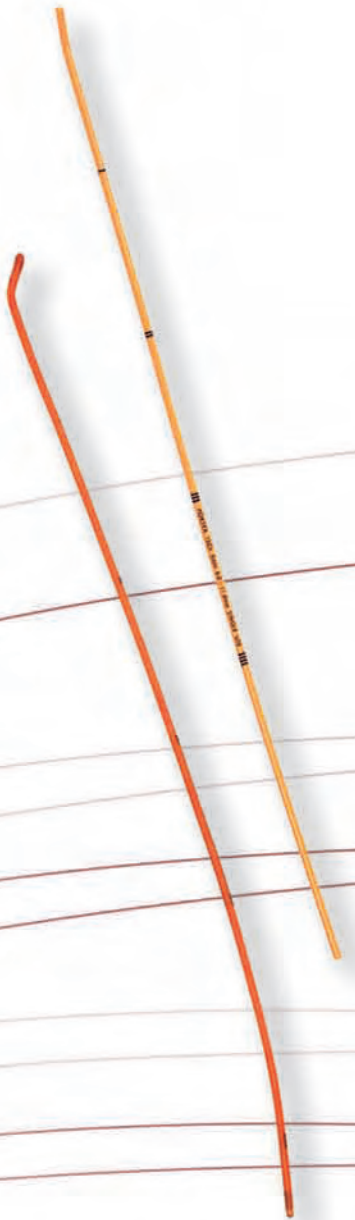
# Intubation Accessories

## 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
<b>Single use</b>					
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
<b>Reusable - "Bougie"</b>					
Introducer	Coudé	15Ch	600	1	14-504-17
Guide	Straight	10Ch	700	1	14-504-76
Guide	Straight	15Ch	700	1	14-504-68



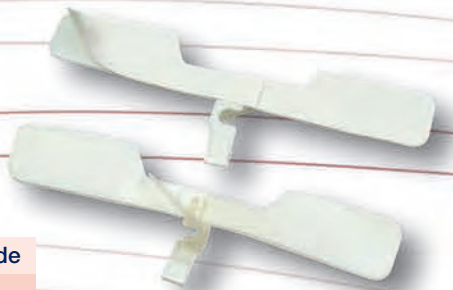
## RSP® Endotracheal Tube holders

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
<b>Neonatal/Paediatric Endotracheal Tube Holders</b>			
	2.5	10	H4051
	3.0	10	H4052
	3.5	10	H4053
	4.0	10	H4054
	4.5	10	H4055
	5.0	10	H4056
<b>Adult Endotracheal Tube Holders</b>			
	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
<b>Neonatal/Paediatric Endotracheal Tube Holders</b>			
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

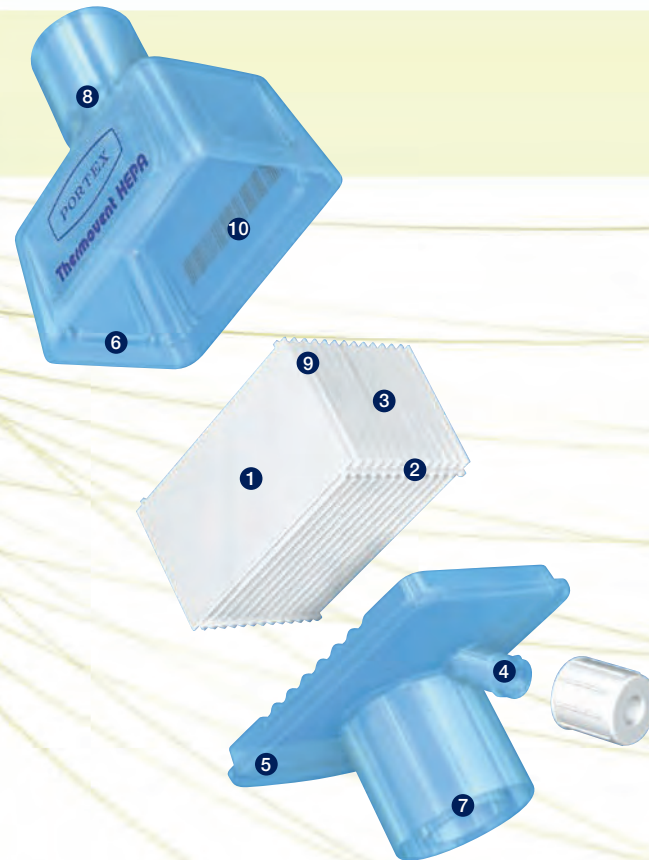


# Thermovent® HEPA Filter

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.



- 1 Hydrophobic filter medium provides protection against liquid and airborne contamination
- 2 Patented even-pleated filter medium allows maximum filtration efficiency with minimal resistance to flow
- 3 Deep pleats ensure consistent gas flow during prolonged clinical use
- 4 Gas sampling port, centrally positioned to ensure accuracy of readings
- 5 Ergonomical design / smooth edges to aid patient comfort
- 6 Transparent housing allows visual confirmation of performance
- 7 15mm/22mm conical connectors to ISO standards
- 8 Anti-disconnect ring (as required by ISO 5356)
- 9 Total encapsulation of all cut edges to avoid fibre shredding
- 10 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

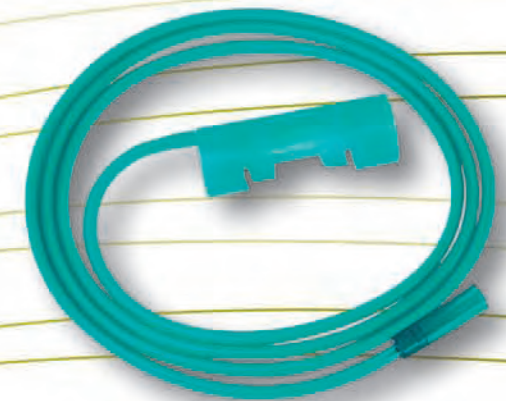
Description	Pack Qty	Product Code
Thermovent T	50	100/570/015

# Thermovent® O<sub>2</sub> -

## 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 <sub>2</sub>	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® CO<sub>2</sub> 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® CO<sub>2</sub> Absorbent

Medical-grade SODASORB® (Soda Lime USP-NF) is the original CO<sub>2</sub> 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 CO<sub>2</sub> 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
<b>Single Lumen</b>				
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
<b>Single Lumen with Catheter Mount</b>				
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
<b>Dual Lumen</b>				
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
<b>Closed Ventilation Suction Systems</b>				
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

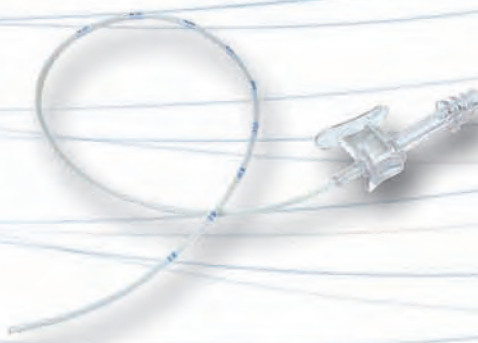


### Ordering information

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

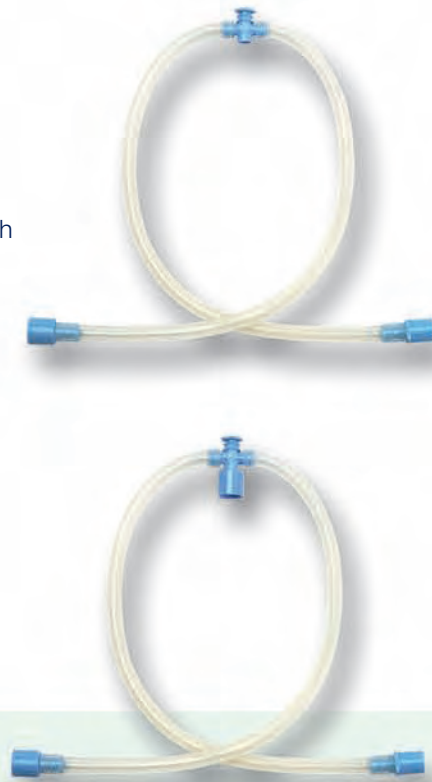
### Ventilation/Breathing System, Infant

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
<b>Incentive Spirometers</b>		
Incentive Spirometers	20	002000
<b>IPPB Manifolds</b>		
Universal IPPB Manifold with Baffle for Faster nebulisation rate	25	002218A
<b>Single Use Mouthpieces</b>		
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 CO<sub>2</sub> retention

### Ordering information

Description	Pack Qty	Size	Product Code
<b>Endotracheal Tube Connectors with Sideport</b>			
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
<b>Low Dead Space Endotracheal Tube Connectors with Sideport</b>			
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 CO<sub>2</sub> 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 H<sub>2</sub>O.
- Disposable Manometer lightweight and easy to use. Two scales measuring normal PEEP and peak inspiratory pressure. Convenience, reliable and accurate.



Manometer

### 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 40cmH<sub>2</sub>O.
- 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 CO<sub>2</sub> Clip™

- Smiths Medical CO<sub>2</sub> Clip™ Colourmetric Carbon Dioxide Detection System. The fast responding sensor that detects the inspiratory and expiratory CO<sub>2</sub> concentration breath - by - breath.



### Product Ordering information

#### Smiths Medical CO<sub>2</sub> Clip™ Ordering Information

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

#### Smiths Medical CO<sub>2</sub> Clip™ with 1st Response™ Manual Resuscitators Ordering Information

Ref Code	Description	Units Per Case
<b>Adult</b>		
8500CE	Adult resuscitator with tethered dust cap, reservoir bag, adult mask, CO <sub>2</sub> Clip™	12
8503CE	Adult resuscitator with tethered dust cap, 40" (101 cm) flexible tubing reservoir, adult mask, CO <sub>2</sub> Clip™	12
<b>Paediatric</b>		
8520CBE	Paediatric resuscitator with tethered dust cap, reservoir bag, child mask, CO <sub>2</sub> Clip™	9
8520CE	Paediatric resuscitator with tethered dust cap, 40" (101 cm) flexible tubing reservoir, child mask, CO <sub>2</sub> Clip™	9
<b>Infant</b>		
8528CMBE	Infant resuscitator with tethered dust cap, reservoir bag, infant and neonate mask, CO <sub>2</sub> Clip™	9
8528CME	Infant resuscitator with tethered dust cap, 18" (46 cm) flexible tubing reservoir, infant and neonate mask, CO <sub>2</sub> 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 CO<sup>2</sup> 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/H<sub>2</sub>O 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

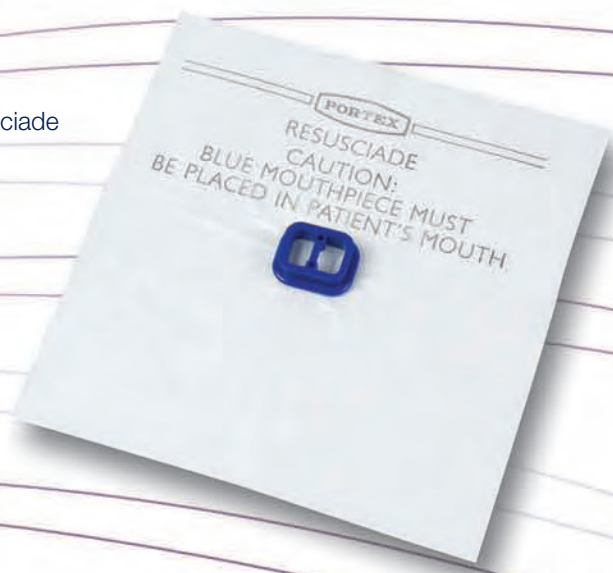
# Resusciade

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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