

CERTIFICAT DE ÎNREGISTRARE

Se certifică prin prezenta că sistemul de management al:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germania

Pentru locații și domenii suplimentare, vedeți anexa

a fost înregistrată de către Intertek deoarece se conformează cerințelor:

EN ISO 13485:2016

Sistemul de management este aplicabil pentru:

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

Service-ul dispozitivelor medicale active.

Certificat Număr:

119-04 C

Data Certificării Inițiale:

08 Iunie 2004

Data Deciziei Certificării:

25 Iunie 2018

Data Emiterii:

25 Iunie 2018

Valabil Până la:

24 Iunie 2021



Semnătura - indescifrabilă

Calin Moldovean

Președinte, Business Assurance

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

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

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

Subsemnata MUSUROIA MIRELA, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii 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 sau prin scanarea codului din dreapta cu un smartphone. Certificatul rămâne proprietatea Intertek, căreia îi trebuie returnat la cerere.





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

No. CE 661325

Issued To: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

United Kingdom

In respect of:

See certificate scope page.

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

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

Stewart Brain, Head of Compliance & Risk -

Medical Devices

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

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Page 1 of 2

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

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





Certificate No: CE 661325

Certificate Scope:

The design, development and manufacture of sterile:

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

The design, development and manufacture of non-sterile:

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

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

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Page 2 of 2

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

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





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





Manufacture

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

Service(s) supplied **Subcontractor:**

Koo Medical Equipment (Shanghai) Co., Ltd 100 Zhongde Road

Dakun Industrial Park

Songjiang, Shanghai 201614

China

Pentair Filtration Solutions **Crucial Supplier**

1350 Hammond Road

St. Paul Minnesota 55110 USA

Quadrant EPP Belgium N.V. **Manufacture**

Industriepark Noord Robert Tavernierlaan 2

Tielt 8700 Belgium





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

List of Significant Subcontractors

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

Certificate No: **CE 661325**Date: **2017-06-28**

Issued To: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

United Kingdom

Subcontractor:

Service(s) supplied

Smiths Healthcare Manufacturing

SA de CV

Avenida Calidad No.4

Parque, Industrial Internacional

Tijuana 22425 Mexico Manufacture

Smiths Healthcare Manufacturing SA de CV

Carretera Miguel Alemán Km 21.7

Parque Industrial Monterrey

Apodaca

Nuevo León

66603 Mexico Manufacture





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

List of Significant Subcontractors

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

Certificate No: **CE 661325**Date: **2017-06-28**

Issued To: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

United Kingdom

Subcontractor: Service(s) supplied

Smiths Medical ASD Inc. 10 Bowman Dr.

Keene

New Hampshire

New Har 03431 USA

Smiths Medical ASD Inc. Manufacture

1265 Grey Fox Road

St Paul Minnesota 55112 USA

Manufacture

Manufacture

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





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

List of Significant Subcontractors

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

Certificate No: **CE 661325**Date: **2017-06-28**

Issued To: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

United Kingdom

Subcontractor: Service(s) supplied

Smiths Medical ASD Inc. 6250 Shier Rings Road

Dublin Ohio 43016 USA

Distribution

Smiths Medical ASD Inc. 9124 Polk Lane, Suite 101

Olive Branch Mississippi 38654 USA

Smiths Medical Czech Republic a.s.

Olomoucká 306 753 01 Hranice Czech Republic Manufacture

Manufacture





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

List of Significant Subcontractors

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

Certificate No: **CE 661325**Date: **2017-06-28**

Issued To: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

United Kingdom

Subcontractor: Service(s) supplied

Smiths Medical Gary 5700 W 23rd Ave Gary

Indiana 46406 USA

Smiths Medical International Ltd Manufacture

52 Grayshill Rd Cumbernauld Glasgow G68 9HQ United Kingdom

Smiths Medical International

Nijmegen Bijsterhuizen 22-08 6604 LD Wijchen The Netherlands Distribution

Manufacture





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

ETO Sterilization

Packaging

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

Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom **ETO Sterilization**





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:

Sterigenics US, LLC 344 Bonnie Circle

Corona California 92880

Sterigenics, LLC 1700 College Blvd. West Memphis

Arkansas 72301

USA

USA

Sterilization Services of

Tennessee, Inc 2396 Florida Street Memphis

Tennessee 38109

USA

Service(s) supplied

Gamma Sterilization

Gamma Sterilization

ETO Sterilization





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

ETO Sterilization

STERIS ISOMEDIX Services, Inc 7685 Saint Andrews Avenue San Diego

California 92154

USA

Mexico

78.59

Manufacture

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

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





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.

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.

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





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

Objectul certificatului:

Proiectarea, dezvoltarea si fabricatia produselor sterile:

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

Proiectarea, dezvoltarea si fabricatia de produse nesterile:

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



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

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Pagina 2 of 2

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

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





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325 Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Servicii prestate

Fabricatie

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

Marea Britanie

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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Pagina 1 din 9

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.





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325

Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Servicii prestate

Fabricatie

Koo Medical Equipment (Shanghai)

Co., Ltd

100 Zhongde Road Dakun Industrial Park Songjiang, Shanghai 201614

China

Pentair Filtration Solutions 1350 Hammond Road

St. Paul Minnesota

55110 USA **Furnizor crucial**

Fabricatie

Quadrant EPP Belgium N.V.

Industriepark Noord Robert Tavernierlaan 2

Tielt

8700

Belgia

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Pagina 2 din 9

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.





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325

Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Smiths Healthcare Manufacturing

SA de CV

Avenida Calidad Nr.4

Parque, Industrial Internacional

Tijuana 22425 Mexic

Smiths Healthcare Manufacturing

SA de CV

Carretera Miguel Alemán Km 21.7

Parque Industrial Monterrey

Apodaca

Nuevo León

66603

Mexic

Servicii prestate

Fabricatie

Fabricatie

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Pagina 3 din 9





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325

Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Servicii prestate

Fabricatie

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

Smiths Medical ASD Inc. 201 West Queen St., Southington

Connecticut 06489

USA

Fabricatie

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Pagina 4 din 9





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325

Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Servicii prestate
Fabricatie

Smiths Medical ASD Inc. 6250 Shier Rings Road

Dublin Ohio 43016 USA

Smiths Medical ASD Inc.

Distributie

9124 Polk Lane, Suite 101 Olive Branch Mississippi 38654 USA

Smiths Medical Republica Ceha a.s.

Olomoucká 306 753 01 Hranice Republica Ceha **Fabricatie**

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Pagina 5 din 9





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325 Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Smiths Medical Gary 5700 W 23rd Ave

Gary Indiana 46406

USA

Smiths Medical International Ltd

52 Grayshill Rd Cumbernauld Glasgow G68 9HQ Marea Britanie

Smiths Medical International

Niimegen Bijsterhuizen 22-08 6604 LD Wijchen

Olanda

Servicii prestate

Fabricatie

Fabricatie

Distributie

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Pagina 6 din 9





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325

Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Smiths Medical Italia Srl Via della Stazione, 2

Latina Scalo
04100

Italia

Sterigenics Belgium (Petit-Rechain) SA

Zoning Industriel de Petit-Rechain

Avenue Andre Ernst 21

B-4800 Verviers

Belgium

Sterilizare ETO

Servicii prestate

Sterilizare ETO

Ambalare

Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ

Marea Britanie

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Pagina 7 din 9





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325

Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Sterigenics US, LLC

344 Bonnie Circle Corona

California 92880

USA

Sterigenics, LLC

1700 College Blvd. West Memphis

Arkansas 72301

USA

Sterilization Services of

Tennessee, Inc 2396 Florida Street

Memphis

Tennessee 38109

USA

Servicii prestate

Sterilizare cu raze gamma

Sterilizare cu raze gamma

Sterilizare ETO

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Pagina 8 din 9





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

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatiile aferente produsului certificat prin:

Certificat nr.: CE 661325

Data: 2017-06-28

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Subcontractant:

Servicii prestate
Sterilizare ETO

STERIS ISOMEDIX Services, Inc 7685 Saint Andrews Avenue

San Diego California 92154

USA

Fabricatie

Avenida La Cuspide #1
Parque Industrial Tecnomex
Del. Playas de Tijuana
Tijuana

Baja California 22700

Mexic

Furnizor crucial

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

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Pagina 9 din 9





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 |
|---------|-----------------------|---|
| | | Prima editie. Transferat de alt organ de certificare. |
| Curenta | 8603169 | Reinnoirea certificatului. |



Pagina 1 of 1

...making excellence a habit."

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.





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 |



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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.

Date: 2017-06-28

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

First Issued: 2017-06-28





EC Design-Examination Certificate

Supplementary Information to CE 661326

Issued To: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

United Kingdom

Certificate History

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

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

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Page 3 of 3

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

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





Certificat CE de examinare a proiectului

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

Nr. CE 661326

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

Marea Britanie

Obiectul certificatului:

Catetere cardiotoracice.

BSI a examinat dispozitivele de mai sus conform cerintelor Directivei Consiliului 93/42/CEE, Anexa II, Sectiunea 4. Proiectul indeplineste cerintele Directivei. Pentru lansarea pe piata a acestor produse, este necesar certificatul mentionat in Anexa II, excluzand Sectiunea 4.

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

Stewart Brain, Sef compartiment conformitate si risc

Dispozitive medicale

Prima editie: 2017-06-28 Data: 2017-06-28

Pagina 1 din 3

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Data expirarii: 2022-06-27

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

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

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





Certificat CE de examinare a proiectului

Informatii suplimentare pentru CE 661326

Smiths Medical International Ltd. Titular:

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 |

Data: 2017-06-28

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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.

Data expirarii: 2022-06-

Prima editie: 2017-06-28





Certificat CE de examinare a proiectului

Informatii suplimentare pentru CE 661326

Titular: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Marea Britanie

Istoricul Certificatului

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

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

Pagina 3 din 3

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

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

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





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.





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

Manufacture

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

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

Taiwan

Manufacture





Manufacture

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

Pentair Filtration Solutions Crucial Supplier

1350 Hammond Road

St. Paul Minnesota 55110 USA

Quadrant EPP Belgium N.V. Manufacture

Industriepark Noord Robert Tavernierlaan 2

Tielt 8700 Belgium





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

List of Significant Subcontractors

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

Certificate No: **CE 661328**Date: **2017-06-28**

Issued To: Smiths Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL

United Kingdom

Subcontractor:

Service(s) supplied

Smiths Healthcare Manufacturing

SA de CV

Avenida Calidad No.4

Parque, Industrial Internacional

Tijuana 22425 Mexico Manufacture

Smiths Healthcare Manufacturing

SA de CV

Carretera Miguel Alemán Km 21.7

Parque Industrial Monterrey

Apodaca

Nuevo León

66603

Mexico

Manufacture





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

New Ha 03431 USA

Smiths Medical ASD Inc. Manufacture

1265 Grey Fox Road

St Paul Minnesota 55112 USA

Manufacture

Manufacture

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





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





Manufacture

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

Smiths Medical International Ltd Manufacture

52 Grayshill Rd Cumbernauld Glasgow G68 9HQ United Kingdom

Smiths Medical International **Distribution**

Nijmegen Bijsterhuizen 22-08 6604 LD Wijchen The Netherlands





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

ETO Sterilization

Packaging

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

Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom **ETO Sterilization**





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:

Sterigenics US, LLC

344 Bonnie Circle Corona California 92880

Sterigenics, LLC 1700 College Blvd. West Memphis

Arkansas 72301 USA

USA

erigenics, LLC Gamma Sterilization

Sterilization Services of Tennessee, Inc

2396 Florida Street

Memphis Tennessee 38109

USA

ETO Sterilization

Service(s) supplied

Gamma Sterilization





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

Tijuana Baja California 22700 Mexico Manufacture

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





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 | First issue. Transferred from another Notified Body. |
| Current | 8603164 | 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.

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.

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





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 III 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.







Certificat Nr.: CE 661328

Domeniu Certificat:

Fabricarea și inspecția finală a următoarelor produse sterile:

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

Fabricarea și inspecția finală a următoarelor produse non-sterile:
Dispozitive de Resuscitare, Tuburi Traheostomie, Sisteme de Intubare.
Acele aspecte din Anexa V cu privire la securitatea și menținerea sterilității Accesoriilor pentru Dispozitivele de Acces Vascular, Dispozitive de Perfuzie de Unică Folosință, Sisteme de Intubare, Dispozitive pentru Obstetrică și Ginecologie.

Prima emitere: **28-06-2017** Data: **28-06-2017** Data expirării: **27-06-2022**

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Pagina 2 din 2

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

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







Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328** Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor Servicii furnizate

Brightwake Limited Fabricare

Lowmoor Business Park

Kirby-in-Ashfield Nottinghamshire

NG17 7JZ Regatul Unit

GaleMed Corporation Fabricare

Nr. 87, Li-Gong 2nd Road

Wu-Jia YILAN 268 Taiwan

GE Medical Fabricare

Pollards Wood Nightingales Lane Chalfont Saint Giles

HP8 4SP Regatul Unit

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Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328** Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

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

Pentair Filtration Solutions 1350 Hammond Road, St. Paul Minnesota 55110 SUA Furnizor Principal

Fabricare

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

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Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328** Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

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

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

Nuevo Leon 66603

Mexic

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Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Ânexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328**Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

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

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

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

.. making excellence a habit." Pagina 4 din 9







Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Ânexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328**Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

Pagina 5 din 9

Smiths Medical ASD Inc., 6250 Shier Rings Fabricare Road, Dublin, Ohio 43016 SUA

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

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

SUA

Republica Cehă

Fabricare

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Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328** Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

Smiths Medical Gary, 5700 W 23rd Ave Fabricare Gary, Indiana 46406

SUA

Smiths Medical International Ltd., 52 Fabricare Grayshill Rd., Cumbernauld, Glasgow G68

9HQ

Regatul Unit

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

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Belgia



Certificat CE – Asigurarea Calității Producției

Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328**Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

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

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

Sterigenics UK Limited, Cotes Park Estate, Sterilizare ETO Somercotes Alfreton, DE55 4NJ Regatul Unit

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Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328** Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

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

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

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

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Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa V

Lista Principalilor Subantreprenori

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

Certificat Nr.: **CE 661328** Data: **28-06-2017**

Emis pentru: Smith Medical International Ltd.

Boundary Road

Hythe Kent CT21 6JL Regatul Unit

Subantreprenor

Servicii furnizate

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

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

.. making excellence a habit." Pagina 9 din 9







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. |

.. making excellence a habit." Pagina 1 din 1

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

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

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

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

Traducător autorizat Nr. 2769/2015



Certificate of Registration



This is to certify that the quality management system of

SMITHS MEDICAL INTERNATIONAL LIMITED

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

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

requirements of: **EN ISO 13485:2012**

The quality management system is applicable to:

Design of:

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

Additional Site:

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

Certificate Number: 053-01 B

Initial Certification Date: 20 October 2005
Certificate Effective Date: 23 July 2016
Certificate Expiry Date: 22 July 2019



Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK This certificate is the property of AMTAC Certification Services Ltd

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited. AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061. In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.



The certificate remains the property of Intertek, to whom it must be returned upon request.

Certificat de Înregistrare



Prin prezenta se certifică faptul că sistemul de management al calității al

SMITHS MEDICAL INTERNATIONAL LIMITED

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

a fost evaluat și înregistrat de AMTAC Certification Services Limited ca fiind conform cerințelor:

EN ISO 13485:2012

Sistemul de management al calității este aplicabil pentru:

Proiectarea:

Sistemelor de Respirat, Dispozitivelor de Drenaj, Dispozitivelor de Alimentare, Dispozitivelor de Filtrare, Infuzoare de Unică Folosință, Sisteme de Intubare, Dispozitive de Obstetrică și Ginecologie, Dispozitive de Management al Oxigenului și Umidității, Dispozitive de Monitorizare a Presiunii, Dispozitive Mecanice de Respirație, Dispozitive de Resuscitare, Catetere Sucțiune, Tuburi Traheotomie, Dispozitive Acces Vascular, Catetere Cardio Toracice și Comprese Chirurgicale

Poziții Suplimentare:

Resurse Umane și Pregătire Profesională, Transport, Cerere Planificare, Supraveghere Post Piață, Cunoașterea Pieței, E-Business, Servicii Client Internațional, Dezvolatre Afacere, Înregistrări, Finanțe, Wallace Women's Healthcare

Certificat Număr: Inițial Data

053-01 B

Certificării: Dată Efectivă

20 Octombrie 2005

Certificat:

23 Iulie 2016

Data Expirării Certificatului:

22 Iulie 2019

Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK

Acest certificat este proprietatea AMTAC Certification Services Ltd

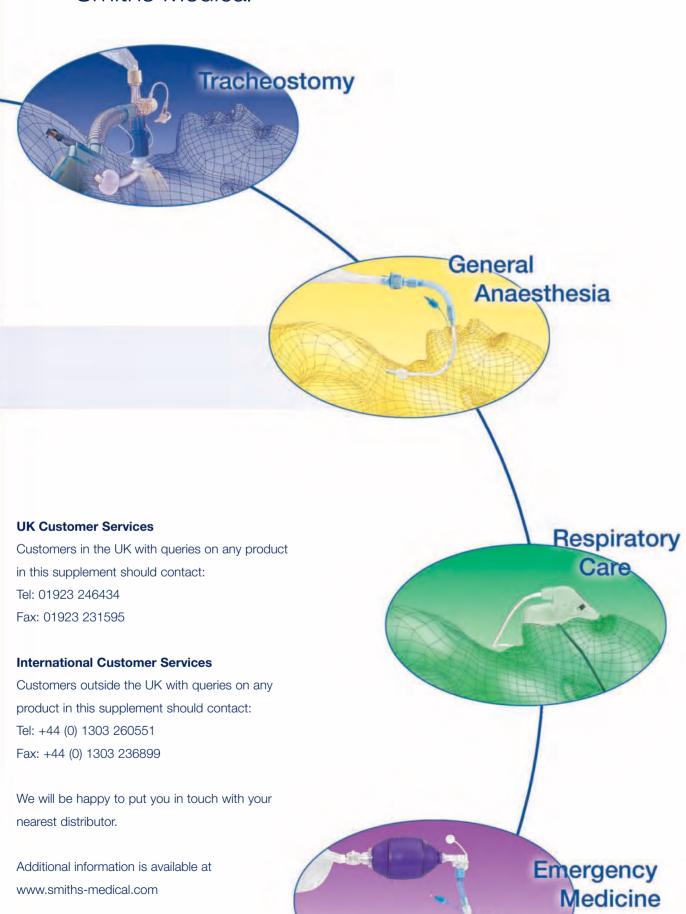
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Smiths Medical



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





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

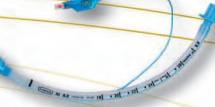
- Smooth, tapered membrane cuff shape ensures minimum contact with the sensitive tracheal mucosa
- Reduces movement relative to trachea during ventilation
- Low pressure responds rapidly to varying pressures during the respiratory cycle
- Streamlined shape reduces risk of creasing on inflation and minimises 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 reuseable airway devices are cleaned, there still may be residual protein deposits which have the potential for disease transmission¹.
- "...our findings prompt us to seriously question the safety of re-using instruments such as the laryngeal mask airway...Even following the guidelines for cleaning this equipment may be insufficient to protect patients from transmission of iatrogenic disease."1
- With the single-use Soft Seal Laryngeal Mask, all possibility of betweenpatient cross-infection is eliminated.
- Ease of access The Soft Seal Laryngeal Mask has been designed to remove the need for epiglottis bars, allowing ease of access for fibre optic devices and the fibre optic guided placement of endotracheal tubes.
- A clear view With the translucent tubing of the Soft Seal Laryngeal Mask condensation is clearly visible to confirm correct mask placement.

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



Ordering information

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

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

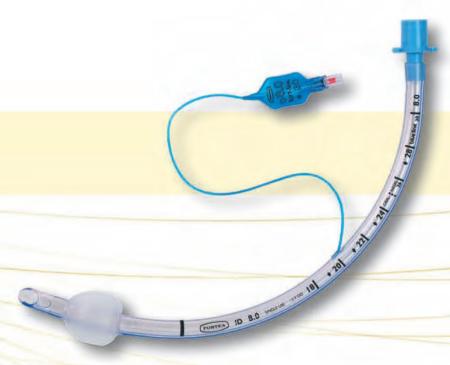
> 2 Lumb, A.B, Wrigley M.W, The effect of nitrous oxide on laryngeal mask cuff pressure. In vitro and in vivo studies. Anaesthesia, 1992, 47: 320-3

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

| | 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

| | | Pack | |
|-----------|-----------|------|--------------|
| I.D. (mm) | O.D. (mm) | 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/***

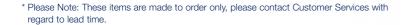
Magill Tubes - Uncuffed

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

| 0 | | | |
|-----------|-----------|----------|---------------------|
| 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

13

| 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.

14

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

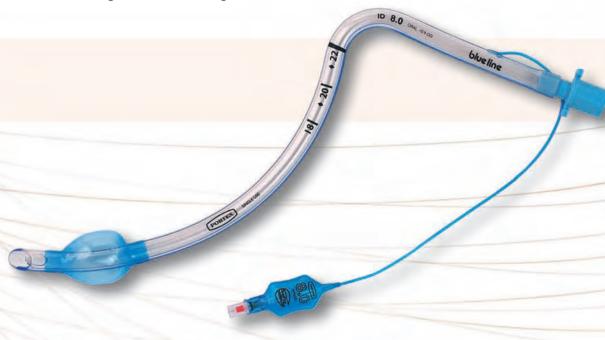
Intubation Specialist Tubes

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 |
| 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

| O.D. (mm) | Cuff Resting Length (cm) | Diameter (mm) | Pack Qty | Product Code |
|-----------|-----------------------------|---|---|---|
| 8.8 | 27.0 | 23 | 10 | 100/133/060 |
| 9.4 | 27.5 | 23 | 10 | 100/133/065 |
| 10.2 | 28.5 | 30 | 10 | 100/133/070 |
| 10.8 | 29.5 | 30 | 10 | 100/133/075 |
| 11.6 | 30.5 | 30 | 10 | 100/133/080 |
| | 8.8 9.4 10.2 10.8 | O.D. (mm) Length (cm) 8.8 27.0 9.4 27.5 10.2 28.5 10.8 29.5 | O.D. (mm) Length (cm) Diameter (mm) 8.8 27.0 23 9.4 27.5 23 10.2 28.5 30 10.8 29.5 30 | O.D. (mm) Length (cm) Diameter (mm) Qty 8.8 27.0 23 10 9.4 27.5 23 10 10.2 28.5 30 10 10.8 29.5 30 10 |

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

| 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

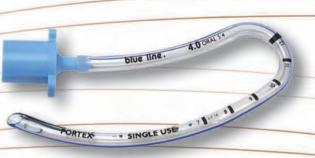
Ordering information

| 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

| O.D. (mm) | Tip to Incisor | Pack | Product Code | |
|--------------|--|--|---|--|
| O.D. (IIIII) | Length (Citi) | Qty | Floudet Code | |
| 4.2 | 10.5 | 10 | 100/134/030 | |
| 4.8 | 11.0 | 10 | 100/134/035 | |
| 5.4 | 12.0 | 10 | 100/134/040 | |
| 6.2 | 13.5 | 10 | 100/134/045 | |
| 6.8 | 14.0 | 10 | 100/134/050 | |
| 7.5 | 14.5 | 10 | 100/134/055 | - |
| 8.2 | 15.0 | 10 | 100/134/060 | |
| 8.8 | 16.0 | 10 | 100/134/065 | |
| 9.6 | 17.5 | 10 | 100/134/070 | |
| 10.2 | 19.0 | 10 | 100/134/075 | |
| | 4.8 5.4 6.2 6.8 7.5 8.2 8.8 9.6 | O.D. (mm) Length (cm) 4.2 10.5 4.8 11.0 5.4 12.0 6.2 13.5 6.8 14.0 7.5 14.5 8.2 15.0 8.8 16.0 9.6 17.5 | O.D. (mm) Length (cm) Qty 4.2 10.5 10 4.8 11.0 10 5.4 12.0 10 6.2 13.5 10 6.8 14.0 10 7.5 14.5 10 8.2 15.0 10 8.8 16.0 10 9.6 17.5 10 | O.D. (mm) Length (cm) Qty Product Code 4.2 10.5 10 100/134/030 4.8 11.0 10 100/134/035 5.4 12.0 10 100/134/040 6.2 13.5 10 100/134/045 6.8 14.0 10 100/134/050 7.5 14.5 10 100/134/055 8.2 15.0 10 100/134/060 8.8 16.0 10 100/134/070 |



• Silicone rubber construction allows multiple tube reuse by autoclaving

• The range of uncuffed tubes covers paediatric sizes

Ordering information

| <u> </u> | | DI: 11 (6.1 | 0 % 1 14 ''' | 0 % 1 14 1 5 |
|-----------|-------------|--------------------------------|--------------------------------|------------------------------------|
| 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 |
| 9.5 | 13.3 | 31 | 10 | 7500095 |

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

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

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





Reinforced ET Tubes - Bivona

Cuffless Wire Reinforced Silicone Endotracheal Tube

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

Ordering information

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

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

Silicone ET Tubes - Bivona

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

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

Ordering information

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



- 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 | | |



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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 |



- 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 |
|----|-----------|-----------|-------------|----------|---------------------|
| ١. | 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





| FR Size | Туре | 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 |



2 5

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

| 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, fibreoptic cap

Ordering information

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

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

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

Ordering information

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

Uncuffed Neonatal/Paediatric Endotracheal Tubes

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

Ordering information

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

Airways

Airways - Disposable

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

| Length (cm) | Pack Qty | Product Code |
|-------------|----------------------------------|---|
| 5.0 | 50 | 100/320/200 |
| 6.0 | 50 | 100/320/100 |
| 7.0 | 50 | 100/320/010 |
| 9.0 | 50 | 100/320/020 |
| 10.0 | 50 | 100/320/030 |
| 11.0 | 50 | 100/320/040 |
| | 5.0 6.0 7.0 9.0 10.0 | 5.0 50 6.0 50 7.0 50 9.0 50 10.0 50 |



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 |



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 inference.

INTUBATION SPECIALIST

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 Seperate Item with Tapes Product Code | Ivory PVC Oral/Nasal Tracheal Tube with Holder Product Code | Siliconised PVC Oral/ Nasal Tracheal Tube with Holder Product Code |
|--------------|-------------|--|--|---|
| 2.0 | 10 | - | - | 100/611/020 |
| 2.5 | 10 | 100/603/025 | 100/605/025 | 100/611/025 |
| 3.0 | 10 | 100/603/030 | 100/605/030 | 100/611/030 |
| 3.5 | 10 | 100/603/035 | 100/605/035 | 100/611/035 |
| 4.0 | 10 | 100/603/040 | 100/605/040 | 100/611/040 |
| 4.5 | 10 | 100/603/045 | 100/605/045 | 100/611/045 |

Individually double packed with 15mm connector inserted

Intubation Stylet, Tracheal Type

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

Ordering information

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

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

Intubation Accessories

Tracheal Tube Introducers and Guides

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

Ordering information

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

RSP® Endotracheal Tube holders

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

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

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

Intubation Accessories

RSP® Neonatal/Paediatric Intubation Sytems and Components

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

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



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

Cuff inflator pressure gauge

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

Ordering information

3 5

| 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

> 99.99999%.* HMEs and filters have ISO standard tapered ends to assure a consistent leak-free seal.

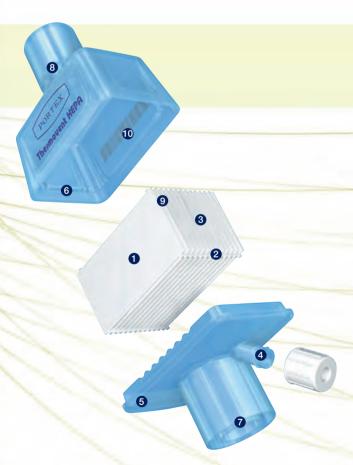
* CAMR, Porton Down, Test Report 444/98 Part 2 Thermovent HEPA

Thermovent® HEPA Filter

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

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

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



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

Ordering information

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

Thermovent® T HME

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

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

Ordering information

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

Thermovent® O₂ -

Oxygen Delivery Aid for Thermovent® T HME

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

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

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







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

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



Ordering information

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

Heat and Moisture Exchangers

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

- High moisture retention and output to retain cilliary 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 |

Anaesthetic Breathing Systems and Accessories

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



Breathing Circuits

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

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



Catheter Mount

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

Ordering information

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

Sodasorb® CO₂ Absorbent

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

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

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



Ordering information

| Pack Qty | Product Code |
|----------|--|
| 12 | 008870 |
| 9 | 008810 |
| 5 | 008850 |
| 12 | 008860 |
| 1 | 088800 |
| 2 | 008871* |
| 12 | 008873 |
| 9 | 008811 |
| 5 | 008851 |
| 2 | 008874* |
| | 12 9 5 12 1 2 12 9 5 |

^{*} 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.

4

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 inflat | ion valve | | | | |
| Adult | Blue | 30 | 5245 | | | |
| Small adult | Yellow | 30 | 5255 | | | |
| Child | Clear | 30 | 5248 | | | |
| Toddler | Green | 30 | 5270 | | | |



Suction Catheters

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

Closed Suction

Steri-cath

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

Single lumen

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

Dual lumen

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

Ordering Information

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

| 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) | 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 | | | |

Respiratory Care

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

SUCTION CATHETERS

Respiratory Care

Ventilation/Breathing System, Infant

This ventilation/breathing system is simple and safe to use with unconscious or active conscious infants ensuring atruamatic 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 | e 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

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







Respiratory Care

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

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

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

Ordering information

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

Humidifiers, Nebulisers, Incentive Spirometers and IPPB Manifolds

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

Ordering information

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

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Respiratory Care Accessories

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

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 polyproplylene
- 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

| ordoning intoin | | |
|-----------------|----------|--------------|
| 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

| Description | Pack Qty | Product Code | |
|---|----------|--------------|---|
| Connector - Firbreoptic Bronchoscope Swivel | 10 | 100/257/000 | 1 |







Connector - Right Angled, 15mm, Reusable

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



- 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 |



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

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





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

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







'Y' Piece Connector, 15mm

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

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

Ordering information

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

Gas Bag Mount, Non-Occluding Cage, 15mm

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

• Prevents accidental occlusion of the reservoir limbs

Ordering information

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

RSP® Endotracheal Tube Connector, with Sideport

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

Ordering information

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



Emergency Medicine

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

Smiths Medical 1st Response™ Manual Resuscitators

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

Practical, Effective, Flexible Resuscitation From Smiths Medical

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

Practical

- New wider SureGrip™ textured panels, enhance tactile feel and improve security of grip when used with wet hands.
- Complete, single use kits minimise the risk of crossinfection 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.









improved grip

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_oO.
- Disposable Manometer lightweight and easy to use. Two scales measuring normal PEEP and peak inspiratory pressure. Convenience, reliable and accurate.

Flexible

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



PEEP valve

Paediatric & Infant resuscitators

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

Adult Resuscitators

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

Smiths Medical CO₂ Clip™

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



CO, Port

Product Ordering information

| Ref Code | Description | Units Per Case |
|----------------------------------|---|----------------|
| 8530C | $\begin{array}{c} \text{Individually packaged CO}_2 \text{ detectors} \\ \text{with attached airway adapter} \end{array}$ | 12 |
| 8530C-25 | Individually packaged CO_2 detectors with attached airway adapter | 25 |
| Smiths Medical CO ₂ C | $\mathrm{Dip^{TM}}$ with 1st Response TM Manual Resuscitators Ordering Information | ation |
| Ref Code | Description | Units Per Case |
| Adult | | |
| 8500CE | Adult resuscitator with tethered dust cap, reservoir bag, adult mask, CO₂ Clip™ | 12 |
| 8503CE | Adult resuscitator with tethered dust cap, 40" (101 cm) flexible tubing reservoir, adult mask, CO₂ Clip™ | 12 |
| Paediatric | | |
| 8520CBE | Paediatric resuscitator with tethered dust cap, reservoir bag, child mask, CO₂ Clip™ | 9 |
| 8520CE | Paediatric resuscitator with tethered dust cap, 40" (101 cm) flexible tubing reservoir, child mask, CO₂ Clip™ | 9 |
| Infant | | |
| 8528CMBE | Infant resuscitator with tethered dust cap, reservoir bag, infant and neonate mask, CO₂ Clip™ | 9 |
| 8528CME | Infant resuscitator with tethered dust cap, 18" (46 cm) flexible tubing reservoir, infant and neonate mask, CO₂ Clip™ | 9 |
| 8501E | PEEP Valve (range 5 - 20 cm H20) | 12 |
| 8518E | 30 mm Exhalation Port Filter | 40 |
| 008201 | Disposable Manometer | 20 |

Range of Manual Resuscitators with CO2 Clip available Q4 2005

Hyperinflation Systems

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

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



Thumb Control Bleed Valve System

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

Dual Swivel Elbow

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

Multiple Sizes and Configurations

- 0.5ltr and 1.0ltr non-latex bags
- 0.5ltr, 1.0ltr, 2.0ltr and 3.0ltr latex bags
- $\bullet\,$ Available with disposable manometer line, or 40cm/H $_{\!2}{\rm O}$ 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

| Prod | uct 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

| | 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



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.



EMERGENCY MEDICINE

6.5

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

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| 008432DM | 63 | 100/240 | 55 | 100/42064 | 6104 | 45 |
| 008435DM | 63 | 100/250 | 53 | 100/430 15 | 6105 | 46 |
| 0088 | 42 | 100/251 | 53 | 100/431 15 | 6109 | 45 |
| 100/105 | 14 | 100/252 | 54 | 100/57038 | 6110 | 45 |
| 100/107 | 21 | 100/253 | 53 | 100/57538 | 6111 | 45 |
| 100/108 | 21 | 100/254 | 55 | 100/58039 | 6152 | 45 |
| 100/109 | 21 | 100/255 | 55 | 100/58239 | 6153 | 45 |
| 100/110 | 21 | 100/257 | 54 | 100/58537 | 6160 | 45 |
| 100/111 | 12 | 100/259 | 49 | 100/59041 | 6161 | 45 |
| 100/112 | 15 | 100/261 | 57 | 100/59441 | 65W | 27 |
| 100/113 | 21 | 100/262 | 56 | 100/603 | 7500 | 25 |
| 100/120 | 33 | Code No. | Page No. | 100/605 | 75W | 22 |