By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 669121**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

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: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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By Royal Charter

Certificate No: CE 669121

Certificate Scope:

The design, development and manufacture of:

Sterile Disposable infusion kits including cassette, tubes, connectors, needles

Patient warming units

Blood and Fluid Warmers units

Sterile Blood and Fluid Warmers disposables sets

Sterile Central Implantable Access Systems

Sterile Peripheral Implantable Access Systems

Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets.

First Issued: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 USA	**Manufacture**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**

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Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	**Gamma Sterilization**
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	**Design** **Manufacture**

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Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	**Manufacture**
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	**Regulatory Compliance**
Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	**Manufacture**

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Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF United Kingdom	**EU Representative**
Sterigenics US, LLC 10811 Withers Cover Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System

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

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Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**

Date: **2018-05-09**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
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USA

Date	Reference Number	Action
20 July 2017	8691798	First issue, transferred from another notified body.
Current	8893340	Renewal, scope rewording, scope reduction, subcontractor removal, correction of subcontractor address and activities

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

Certificate Number:
119-04 C

Initial Certification Date:
08 June 2004

Date of Certification Decision:
25 June 2018

Issuing Date:
25 June 2018

Valid Until:
24 June 2021

This is to certify that the management system of:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

See appendix for additional sites and additional site scopes

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

EN ISO 13485:2016

The management system is applicable to:

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

The Servicing of active medical devices.

UKAS MANAGEMENT SYSTEMS
061

Calin Moldovean
President, Business Assurance

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

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

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

smiths medical
bringing technology to life

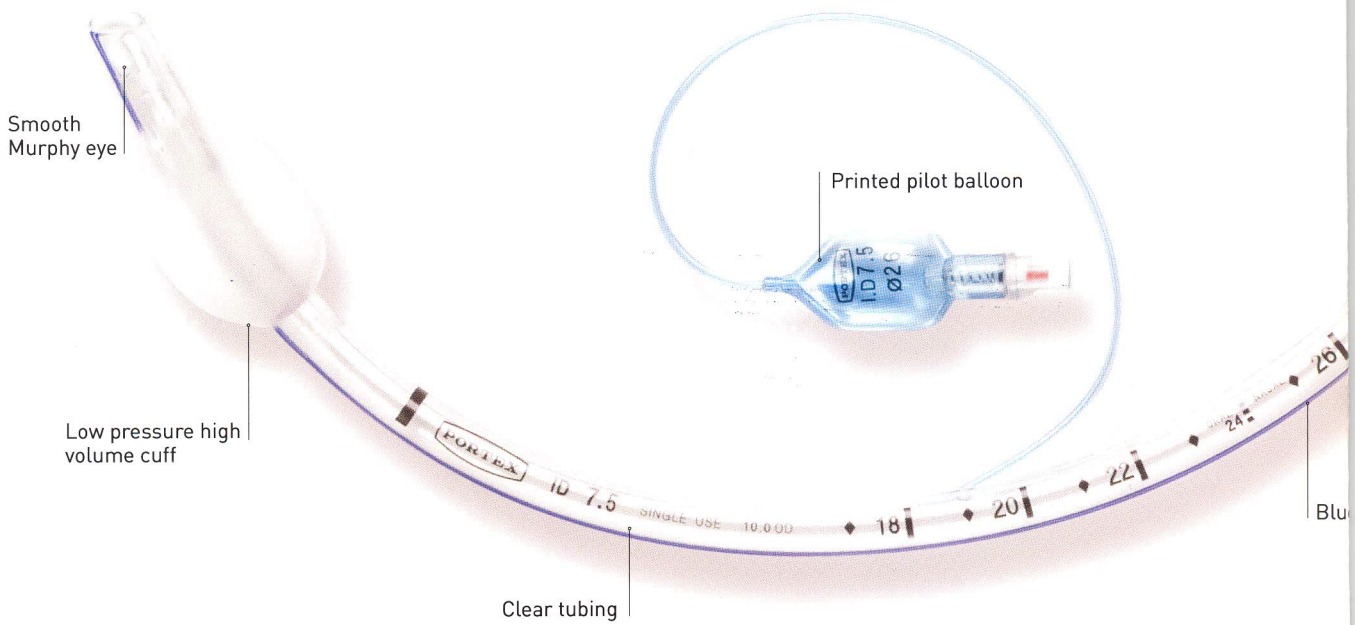
Portex® Choice Tracheal Tubes for the Operating Room

Affordable quality - SMILE!

AIRWAY MANAGEMENT

PORTEX™

PORTEX™



The New Portex® Tracheal Tube

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

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

Affordable quality

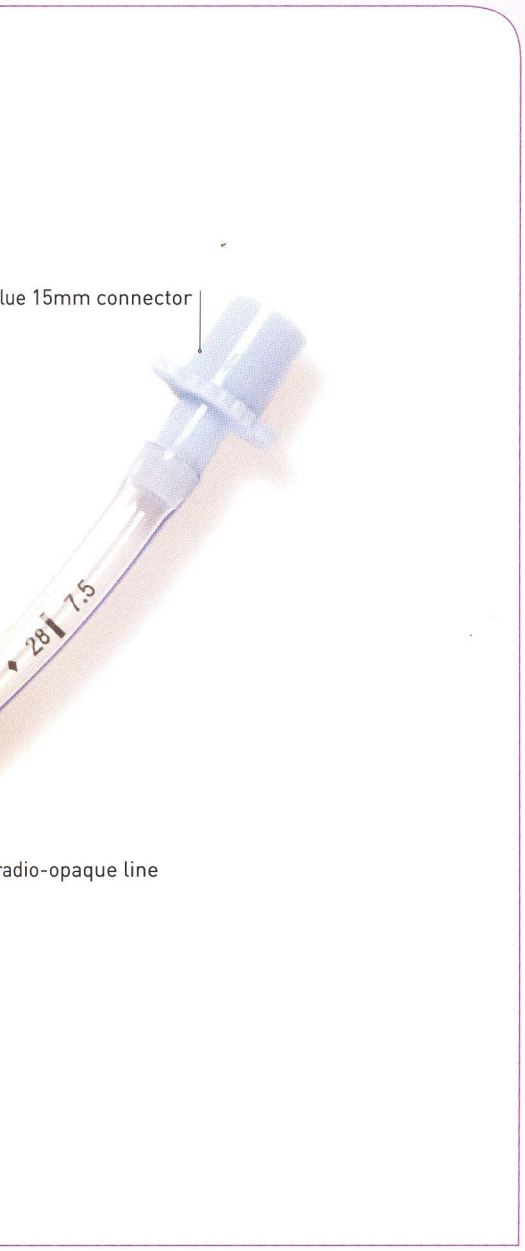
Portex®, a renowned brand in airway products, has created a high quality tracheal tube that incorporates all the superior features expected from a Smiths Medical product, yet at an affordable price.

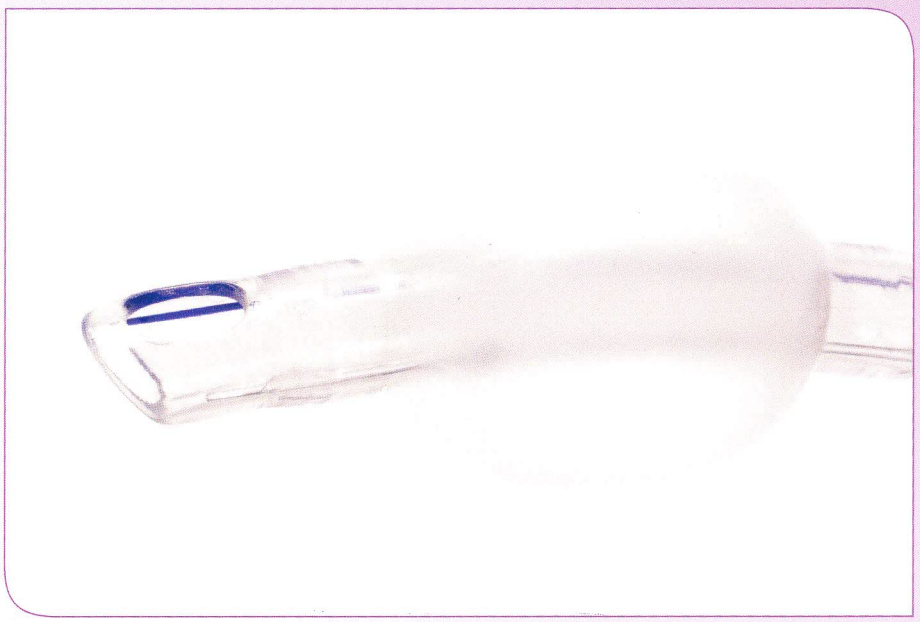
The new Portex® Tracheal Tube is perfect for the majority of all operating room procedures of a short duration.

Low pressure seal

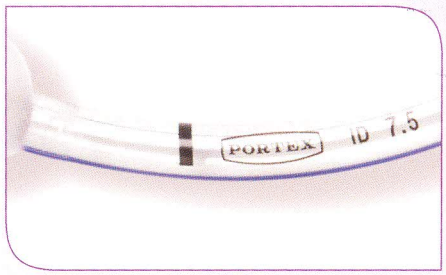
The new Portex® Tracheal Tube has a low pressure, high volume barrel cuff, reducing the risk of creasing on inflation and in turn minimising the pressure on the tracheal wall.

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

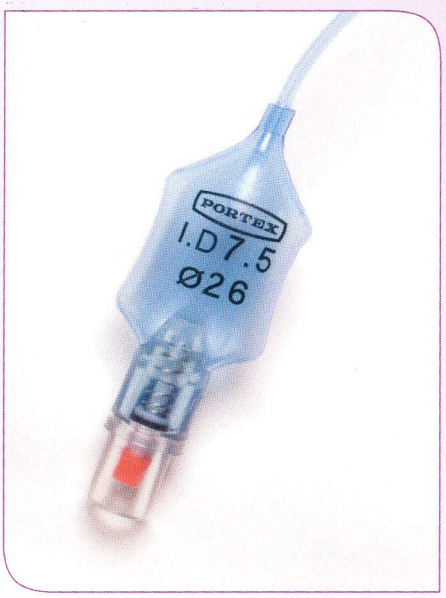




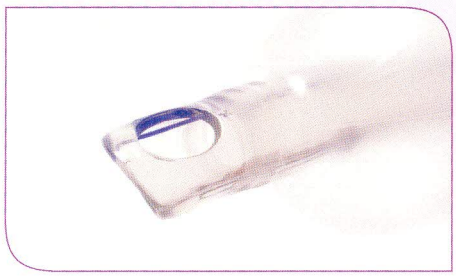
Low pressure high volume cuff



Intubation depth marker



Printed pilot balloon



Smooth Murphy eye

Superior smooth finish

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

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

Easily identifiable

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

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

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

Fully informed

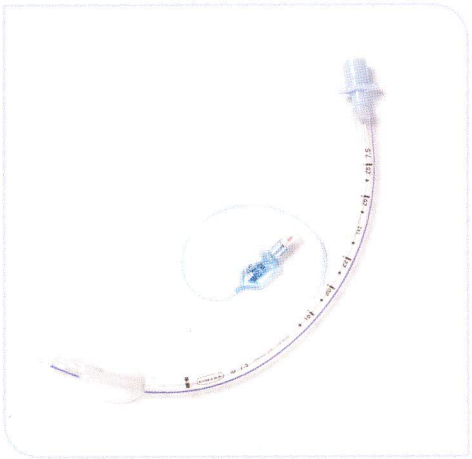
The new Portex® Tracheal tube incorporates a smooth edged pilot balloon that displays the size and maximum inflation pressure allowing for the relevant size to be identified, even when in situ. The balloon changes shape when inflated and contains a central channel so it will not collapse if the cuff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

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

Portex® Choice Tracheal Tube

For short-term intubation within the operating room

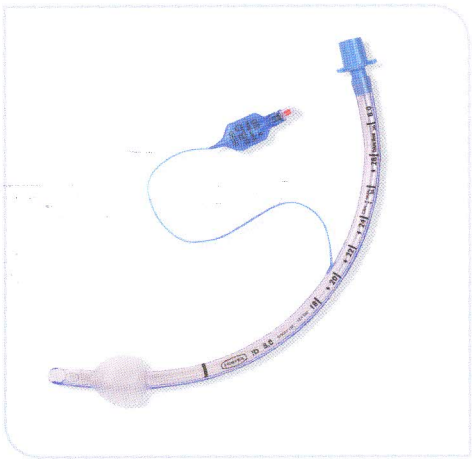
ORDERING INFORMATION				
Product Code	I.D.(mm)	O.D.(mm)	Cuff resting diam.(mm)	Pack Qty
100/150/050	5.0	6.7	22	10
100/150/055	5.5	7.3	22	10
100/150/060	6.0	8.0	24	10
100/150/065	6.5	8.5	24	10
100/150/070	7.0	9.2	26	10
100/150/075	7.5	10.0	26	10
100/150/080	8.0	10.7	28	10
100/150/085	8.5	11.3	28	10
100/150/090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



Portex® Soft Seal® Tracheal Tube

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

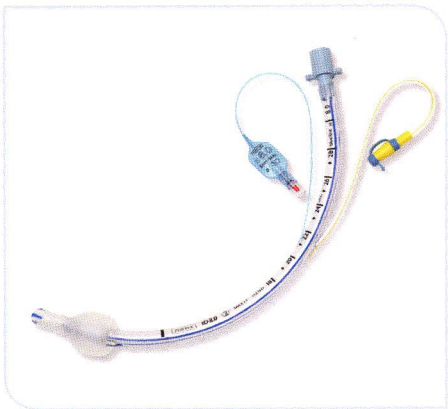
ORDERING INFORMATION				
Product Code	I.D.(mm)	O.D.(mm)	Cuff resting diam.(mm)	Pack Qty
100/199/050	5.0	6.9 mm	25	20
100/199/055	5.5	7.6 mm	28	20
100/199/060	6.0	8.2 mm	29	20
100/199/065	6.5	8.9 mm	30	20
100/199/070	7.0	9.6 mm	31	20
100/199/075	7.5	10.3 mm	32	20
100/199/080	8.0	10.9 mm	33	20
100/199/085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



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

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

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



THE DETAILS GIVEN IN THIS LEAFLET ARE CORRECT AT THE TIME OF GOING TO PRESS. THE COMPANY RESERVES THE RIGHT TO IMPROVE THE EQUIPMENT SHOWN

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www.smiths-medical.com

Literature No. LIT/AM 3051

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