

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016
ISO 9001:2015

Scope:

Sales, order management, warehousing and distribution of medical devices.
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021
Certificate effective date: 1 July 2018
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

Different scope

Medtronic Portugal LDA-
Rua Tomas da Fonseca Torre E, 11
 piso
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices
including technical service and customer education.

Warehousing and distribution of medical devices, including spine
loaner operations

Medtronic Italia S.p.A.
Via Varesina 162
20156 Milano
Italy

Sales, order management and distribution of medical devices.
Including technical service and customer education.
Promotion, invoice and order management of medicinal
products.

Medtronic Danmark A/S.
Arne Jacobsens Allé 17
2300 Copenhagen
Denmark

Sales, order management and distribution of medical devices.
Including technical service and customer education

Medtronic Medikal Teknoloji Ticaret Ltd
Sti
Saray Mah. Esnaf Sk.
Akkom Ofis Park Laodik Plaza
Sitesi B Blok Apt: 2/8
00000 Umraniye - Istanbul
Turkey

Sales, order management and distribution of medical devices.
Including technical service and customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.
Waterfall Distribution Campus
CNR K101 and Bridal Veil Road
Waterfall Midrand
1685 Gauteng
South Africa

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Ibérica S.A.
Calle de María de Portugal, 11
28050 Madrid
Spain

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Romania SRL
Ploiesti 42-44, Building B, B2
Wing, 2nd floor, district 1
Baneasa Business & Technology Park
013696 Bucharest
Romania

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Norge AS
Martin Linges vei 25
1364 Fornebu
Norway

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Portugal, LDA-
Avenida Gomes Pereira 61B
Benfica
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices Including technical service and customer education.

Warehousing and distribution of medical devices, including spine loaner operations.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Service & Repair CoE
C-Mill gebouw K
Jan Campertstraat 21-A
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.
Polígono Industrial La Garena
Calle Francisco Rabal 7
28806 Alcalá De Heneras, Madrid
Spain

Spine loaner operations.

Medtronic Ibérica S.A.
WTC Almeda Park
Placa de la Pau, s/n. Edificio 7, 3 piso
08940 Cornellà de Llobregat, Barcelona
Spain

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS
27/33 Quai Alphonse Le Gallo
92513 Boulogne-Billancourt
France

Sales, order management and distribution of medical devices. Including technical Service and customer education

Medtronic Trading NL B.V.
Larixplein 4
5616 VB Eindhoven

Sales, order management and distribution of medical devices. Including technical service and customer education

Medtronic GmbH
Earl-Bakken-Platz 1
40670 Meerbusch
Germany

Distribution of medical Devices, medical equipment and related services.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Österreich GmbH
Millennium Tower, 20th floor
Handelskai 94-96
1200 Wien
Austria

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic (Schweiz) AG
Talstrasse 9
3053 Munchenbuchsee
Switzerland

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic Hellas S.A.
Avenue Kifisias 24 Building B
151 25 Marousi Pref. Attica
Greece

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Serbia Ltd.
Bulevar Zorana Djindjica, 64a
11070 Belgrade
Serbia

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.
Bocskai út 134-146
Cépulet 3. emelet
1113 Budapest
Hungary

Sales, order management and distribution of medical devices. Including customer education.

Medtronic CCO SSC Warsaw
Polna 11
00-633 Warszawa
Poland

Order management of medical devices.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Finland Oy
Lentäjätie 3
01530 Vantaa
Finland

Sales, order management and distribution of medical devices.
Including technical service and customer education.

Medtronic AB
P.O. Box 1034
164 21 Kista
Sweden

Sales, order management and distribution of medical devices.
Including technical service and customer education

Medtronic Trading Ltd.
10 Hamada Street
4673344 Herzlya
Israel

Import, sales, order management and distribution of medical
devices. Including technical service and customer education

Addendum expiry date: 1 July 2021
Addendum effective date: 1 July 2018



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 077790 0060 Rev. 00

Manufacturer:

Covidien LLC

15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): Oximetry and Capnography Monitor Systems
Temperature Monitor Systems, Patient Warming
Device Systems, Disposable Airway Management
Devices, Tracheal Tubes, Tracheostomy Tubes,
Speaking Valves, and Intubating Stylets, Ventilator
Systems and Patient Interface Circuit Systems,
EEG Monitoring Systems, Breathing Therapy and
Humidification, Heated Inspiratory Line
Humidifiers, Multi-patient Physiologic Monitoring
System and Data Analytics Software,
Gastrointestinal Measurement and Dilation System,
Electrosurgical Diathermy System Electrode.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

72145607

Valid from:

2020-06-29

Valid until:

2024-05-26

Date,

2020-06-29

Christoph Dicks
Head of Certification/Notified Body

QUICK
REFERENCE
GUIDE

AIRWAY MANAGEMENT PRODUCTS

Shiley™ Endotracheal Tubes



Medtronic
Further. Together

Shiley™ endotracheal tube catalog number charts

DESCRIPTION	QTY PER BOX	SIZE (MM)						
		1.0	1.5	2.0	2.5	3.0	3.5	4.0

VENTILATOR-ASSOCIATED PNEUMONIA (VAP) REDUCTION

TaperGuard™ evac oral endotracheal tube, Murphy eye	10							
TaperGuard™ evac oral endotracheal tube, Murphy eye, with pre-loaded stylet								
Evac oral endotracheal tube Seal Guard, Murphy eye	10							

BASIC CUFFED

TaperGuard™ with stylet, endotracheal tube, Murphy eye	10							
TaperGuard™ oral/nasal endotracheal tube, Murphy eye	10							
Oral/nasal endotracheal tube Seal Guard, Murphy eye	10							
Hi-Lo oral/nasal endotracheal tube, cuffed, intermediate, Murphy eye	10					86442	86443	86444
Hi-Lo oral/nasal endotracheal tube, cuffed, hooded Murphy tip with Murphy eye	10							
Lo-Pro oral/nasal endotracheal tube, cuffed, Murphy eye	10					86043		86045
Lo-Pro oral/nasal endotracheal tube cuffed, Magill tip	10					86003		86005

BASIC CUFFLESS

Oral/nasal endotracheal tube, cuffless, Murphy eye	10			86232	86233	86234	86235	86236
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SIZE (MM)											
4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10

			18860	18865	18870	18875	18880	18885	18890		
			18860S	18865S	18870S	18875S	18880S	18885S	18890S		
			110860	110865	110870	110875	110880	110885	110890		

	18750S	18755S	18760S	18765S	18770S	18775S	18780S	18785S	18790S		18710S
	18750	18755	18760	18765	18770	18775	18780	18785	18790		18710
	109850	109855	109860	109865	109870	109875	109880	109885	109890		109810
86445	86446	86447	86448	86449	86450	86451	86452	86453	86454	86455	86456
	86107	86108	86109	86110	86111	86112	86113	86114	86115		86117
86046	86047	86048	86049	86050	86051	86052	86053	86054	86055	86056	86057
	86007		86009	86010	86011	86012	86013	86014	86015	86016	86017

86237	86238	86239	86240	86241	86242						
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Shiley™ endotracheal tube catalog number charts (cont'd.)

DESCRIPTION	QTY PER BOX	SIZE (MM)						
		1.0	1.5	2.0	2.5	3.0	3.5	4.0

RAE CUFFED AND CUFFLESS

Shiley™ oral RAE endotracheal tube with TaperGuard™ cuff	10							
Oral RAE endotracheal tube, cuffed, Murphy eye	10							86209
Oral RAE endotracheal tube, cuffless, Murphy eye	10							
Shiley™ nasal RAE endotracheal tube with TaperGuard™ cuff	10							
Nasal RAE endotracheal tube, cuffless, Murphy eye	10					86283	86284	86285

SPECIALTY CUFFED AND CUFFLESS

Oral/nasal endotracheal tube, cuffed reinforced, Murphy eye	5							
Endotracheal tube cuffless, reinforced, Magill tip	5				86541	86542	86543	86544
Laser oral/nasal endotracheal tube, dual cuffed, Murphy eye	5							
Laser oral/nasal endotracheal tube, cuffless, Magill tip	5					86400	86401	86402
Microlaryngeal oral/nasal endotracheal tube, cuffed, Murphy eye	10							86385

McGRATH™ MAC VIDEO LARYNGOSCOPE

DESCRIPTION	QTY PER BOX	SIZE (MM)	SKU NO.
Handle	1	N/A	301-000-000
McGRATH™ MAC blade size 1	50	1.0	350-072-000
McGRATH™ MAC blade size 2	50	2.0	350-017-000
McGRATH™ MAC blade size 3	50	3.0	350-005-000
McGRATH™ MAC blade size 4	50	4.0	350-013-000
McGRATH™ MAC X blade size 3	10	3.0	X3-003-000
250-minute battery pack	1	N/A	340-000-000

SIZE (MM)											
4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10

	76251	76255	76260	76265	76270	76275	76280	76285	76290		
86199											
86266	86267	86268	86269	86270	86271						
			96360	96365	96370	96375	96380				
86286	86287	86288	86289	86290	86291						

			86548	86549	86550	86551	86552	86553	86554	86555	
86545	86546	86547									
86397	86394	86395	86398								
	86387		86389								

Shiley™ endotracheal tube catalog number charts (cont'd.)

DESCRIPTION	QTY PER BOX	SIZE (MM)		
		24	26	28

ENDOBONCHIAL TUBES

Endobronchial tube, left	1			125028
Endobronchial tube, right	1			
Endobronchial tube, left with carinal hook	1			
Endobronchial tube, left with CPAP	1			125128
Right with CPAP system	1			
CPAP system for dual-lumen endotracheal tube (catalog no. 85006)	5			

ESOPHAGEAL/ENDOTRACHEAL DOUBLE-LUMEN AIRWAY

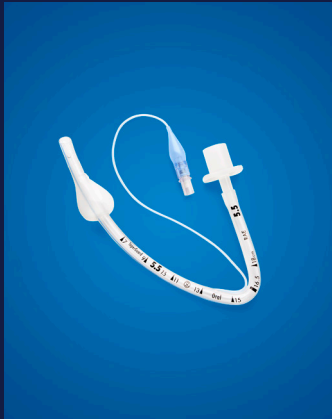
Use size 37 for patients 4' to 5'6" tall
Use size 41 for patients 5' tall and above

Esophageal/endotracheal double-lumen airway with X-ray line	4			
Esophageal/endotracheal double-lumen airway single line	4			
Esophageal/endotracheal double-lumen airway rollup kit line	4			
Esophageal/endotracheal double-lumen airway trainer, not for human use, mannequin demonstrations only	1			
Nasopharyngeal airway	10	8888-247015	8888-247023	8888-247031

SIZE (MM)						
30	32	34	35	37	39	41

	125032		125035	125037	125039	125041
			126035	126037	126039	126041
			125235	125237	125239	125241
	125132		125135	125137	125139	125141
			126135	126137	126139	126141

				5-18537		5-18541
				5-18237		5-18241
				5-18437		5-18441
						5-18141
8888-247049	8888-247056	8888-247064				



TaperGuard™ evac oral endotracheal tube, murphy eye

Incorporates Shiley™ evac technology which has been shown to reduce VAP.¹ Incorporates the TaperGuard™ cuff shown to reduce microaspiration by an average of 90% compared to the Shiley™ Hi-Lo cuff.²

TaperGuard™ endotracheal tube with stylet, murphy eye

The Shiley™ oral/nasal endotracheal tube with TaperGuard™ cuff and stylet gives you the tools you need in one sterile, easy-to-access pack — no preloading necessary.

Oral RAE endotracheal tube with TaperGuard™ cuff

Preformed curve design intended to reduce kinks and disconnects, maintain a patent airway, and position the circuits and connectors away from the surgical field. Features TaperGuard™ cuff technology.

Nasal RAE endotracheal tube with TaperGuard™ cuff

Preformed curve design positions circuits and connectors away from the surgical field without needing to bend or kink standard straight endotracheal tubes.



TaperGuard™ oral/nasal endotracheal tube, Murphy eye

Unique taper-shaped cuff shown to reduce microaspiration by an average of 90% compared to the Shiley™ Hi-Lo cuff.²



Oral/nasal cuffless endotracheal tubes

Tubes feature distal tip reference marks and depth marks every centimeter to assist placement. Available in precut lengths. Smooth hooded tip with Murphy eye.



Microlaryngeal oral/nasal endotracheal tube

Provides greater access to surgical field during microlaryngeal surgical procedures. Standard tube internal and outside diameters, with longer tube length.



Endobronchial tube

For independent ventilation of either lung. Polyurethane endotracheal cuff is designed to reduce the risk of tearing during intubation. Available in left, right, and left with carinal hook styles.



Reinforced endotracheal tube

Maintains patent airway when patient's head and neck are extended or flexed, when the patient is prone, or when the patient will be moved.



Laser oral/nasal endotracheal tube

Designed for use with CO₂ and KTP laser surgery in close proximity to the airway. Flexible, stainless-steel body is airtight and laser resistant. Beams reflected from tube are defocused to help protect surrounding tissue.



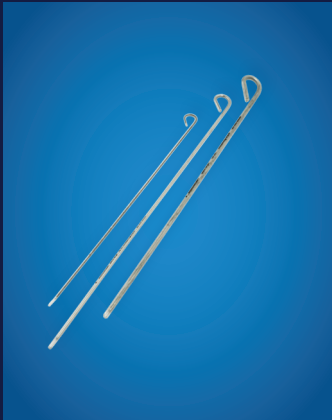
Endobronchial tube with CPAP*

CPAP improves oxygenation during one-lung anesthesia. Adjustable valve provides clinically accurate pressure settings from 1–10 cm H₂O. Complete, ready-to-use system includes anesthesia bag.



Esophageal/endotracheal double-lumen airway

Unique design lets you establish a patent airway when placed in the trachea or esophagus.



Intubating stylet

Facilitates intubation of endotracheal tubes. 20 per box.

<u>Size</u>	<u>Catalog no.</u>
6 Fr	85863
10 Fr	85864
14 Fr	85865



Nasopharyngeal airway

Provides an open airway during suctioning and bronchoscopy. Soft material helps minimize patient coughing and gagging. Protects mucosa for repeated catheter passage.



McGRATH™ MAC enhanced direct laryngoscope

A single handheld device that combines the benefits of:

- Direct laryngoscopy, the familiar technique of a Macintosh laryngoscope
- Video laryngoscope video technology

*The CPAP valve is licensed by Dr. David Alfery.

1. Smulders K, van der Hoeven H, Weers-Pothoff I, Vandenbroucke-Grauls C. A randomized clinical trial of intermittent subglottic secretion drainage in patients receiving mechanical ventilation. *Chest*. 2002;121(3):858-862.
2. Shiley™ TaperGuard™ endotracheal tube and Shiley™ TaperGuard™ Evac endotracheal tube 510(k) #090352 benchtop testing.
3. Shiley™ endotracheal tube Seal Guard and Shiley™ endotracheal tube Seal Guard Evac 510(k) #082520 benchtop testing.

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6135 Gunbarrel Avenue
Boulder, CO 80301

800.635.5267

[medtronic.com](https://www.medtronic.com)

Medtronic