

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Din
От

1

DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal/Numărul de identificare

Фискальный код/Идентификационный номер

Denumirea

Наименование

2

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT/ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ НЕДОИМКИ СОГЛАСНО ДАННЫХ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie/На дату выдачи данной справки, недоимка перед национальным публичным бюджетом составляет

 lei/лей

3

VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО



Prezentul certificat este eliberat în temeiul Art. 131, alin. (5³) din Codul fiscal nr. 1163/1997, în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Antreprenorului/Сертификат выдан в соответствии со ст. 131, п. (5³) Налогового кодекса №1163/1997, на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Предпринимателя

Generat și semnat de Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) la

Prezentul certificat este semnat electronic în conformitate cu Legea nr. 124 din 19.05.2022 /

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022

Certificatul este descărcat de pe Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală.
Verificarea autenticității semnăturii electronice poate fi realizată la adresa: <https://msign.gov.md>.

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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

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:

ISO 9001:2015 EN ISO 13485:2016

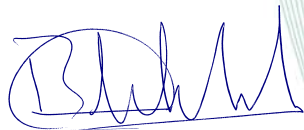
Scope:

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

Certificate expiry date: 1 July 2024
Certificate effective date: 1 July 2021
Certified since: 1 July 2006

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

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
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 Trading NL B.V.
Larixplein 4
5616 VB Eindhoven
The Netherlands

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

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

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

Medtronic Danmark A/S.
Arne Jacobsens Alle 17
2300 Kopenhagen
Denmark

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

Medtronic Finland Oy
Lentajantie 3
01530 Vantaa
Finland

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

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

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

Medtronic Norge AS
Martin Linges vei 25
1364 Fornebu
Norway

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

Medtronic Medikal Teknoloji Ticaret Ltd
Sti
Saray Mah. Esnaf Sk. Akkom Ofis Park
Laodik Plaza Sitesi B Blok Apt: 2/8
34764 Umraniye - Istanbul
Turkey

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

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

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

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

Sales, order management and distribution of medical devices.

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

Sales, Order Management and distribution of medical devices including 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 Portugal, LDA-
Avenida Gomes Pereira 61B
Benfica
1600 Lisboa
Portugal

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

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

Medtronic GmbH
Earl-Bakken-Platz 1
40670 Meerbusch
Germany

Scope for EN ISO 13485:2016: Sales, order management and
distribution of medical devices. Including customer education.
ISO 9001:2015 excluded

Medtronic GmbH
Mollsfeld 12
40670 Meerbusch
Germany

Scope for EN ISO 13485:2016: Sales, order management and
distribution of medical devices. Including customer education.
ISO 9001:2015 excluded

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

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

Medtronic (Schweiz) AG
Talstrasse 9
3053 Munchenbuchsee
Switzerland

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

Medtronic France SAS
9, boulevard Romain Rolland
75014 Paris
France

Sales, order management and distribution of medical devices.
Including 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 Hellas S.A.
Avenue Kifisias 24 Building B
151 25 Marousi Pref. Attica
Greece

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

Medtronic Hellas S.A. Diabetes Shop
Mesogeion Avenue 2-4
115 27 Athens
Greece

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

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 customer education.

Medtronic Hungária Kft.
Bocskai ut 134-146 Cepulet 3. emelet
1113 Budapest
Hungary

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

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

Sales, order management and distribution of medical devices.
Including 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 Poland Sp.z o.o Medtronic
Customer Care Center of Experience
Warsaw
Polna 11
00-633 Warszawa
Poland

Order management of medical devices.

Medtronic Trading Ltd.
10 Hamada Street
4673344 Herzliya
Israel

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

Medtronic Czechia s.r.o.
Prosek Point, Budova B, Prosecka
852/66
852 66 Praha
Czech Republic

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

Medtronic Bulgaria EOOD
48 Sitnyakovo blvd., R-N OBORISHTE
DISTR., floor 7
1505 Sofia
Bulgaria

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

Medtronic Limited
Building 9, Croxley ParkHatters Ln
WD18 8WW Watford
United Kingdom

Sales, order management and distribution of medical devices.
Including 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 Ireland Limited
Block 3090-3094 Lake Drive, Citywest
Business Campus
D24 NW2F Dublin
Ireland

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

Medtronic B.V.
Medtronic Service & Repair EMEA
Jan Campertstraat 21-A
6416 SG Heerlen

Order management, warehousing and technical service of
medical devices including field service EMEA.

Medtronic Slovakia s.r.o.
CBC III, Karadzicova 12
821 08 Bratislava
Slovak Republic

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

Medtronic Belgium
Burgemeester E. Demunterlaan 5
1090 Brussel
Belgium

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

Medtronic Croatia
Folnegoviceva 1c
10000 Zagreb
Croatia

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

Medtronic Slovenia
Ameriska Ulica 8
1000 Ljubljana
Slovenia

Sales, order management and distribution of medical devices

Addendum expiry date: 1 July 2024
Addendum effective date: 1 July 2021

Oral/Nasal Tracheal Tube Cuffed/Cuffless

Standard basic tubes

Tracheal tube and tracheal tube with high volume, low pressure cuff for intubation during short-term intubation in OR and emergency.

FEATURES AND BENEFITS:

- Cuffed tracheal tube with Luer valve and pilot balloon.
- Intubation depth marks and pre-mounted 15 mm connector.
- Tip-to-tip x-ray line allows for safe positioning control.
- Murphy eye incorporated as an additional safety feature.

ORDERING INFORMATION:

REF	Description	I.D. (mm)	O.D. (mm)	Length (mm)	Cuff Ø (mm)
<i>cuffless</i>					
9320E	2.0mm Endotracheal Tube UNCUF	2.0	2.9	130	-
9325E	2.5mm Endotracheal Tube UNCUF	2.5	3.6	140	-
9336E	3.0mm Endotracheal Tube UNCUF	3.0	4.2	160	-
9335E	3.5mm Endotracheal Tube UNCUF	3.5	4.9	180	-
9342E	4.0mm Endotracheal Tube UNCUF	4.0	5.5	200	-
9345E	4.5mm Endotracheal Tube UNCUF	4.5	6.2	220	-
9350E	5.0mm Endotracheal Tube UNCUF	5.0	6.8	240	-
9360E	5.5mm Endotracheal Tube UNCUF	5.5	7.5	270	-
9366E	6.0mm Endotracheal Tube UNCUF	6.0	8.2	280	-
9365E	6.5mm Endotracheal Tube UNCUF	6.5	8.8	290	-
9370E	7.0mm Endotracheal Tube UNCUF	7.0	9.6	310	-
<i>cuffed</i>					
9430E	3.0mm Endotracheal Tube CUFD	3.0	4.2	160	8
9440E	4.0mm Endotracheal Tube CUFD	4.0	5.5	200	11
9450E	5.0mm Endotracheal Tube CUFD	5.0	6.8	240	16
9555E	5.5mm Endotracheal Tube CUFD	5.5	7.5	270	17
9460E	6.0mm Endotracheal Tube CUFD	6.0	8.2	280	22
9465E	6.5mm Endotracheal Tube CUFD	6.5	8.8	290	22
9570E	7.0mm Endotracheal Tube CUFD	7.0	9.6	310	25
9475E	7.5mm Endotracheal Tube CUFD	7.5	10.2	320	25
9480E	8.0mm Endotracheal Tube CUFD	8.0	10.9	320	27
9485E	8.5mm Endotracheal Tube CUFD	8.5	11.5	320	27
9590E	9.0mm Endotracheal Tube CUFD	9.0	12.1	320	29
9495E	9.5mm Endotracheal Tube CUFD	9.5	12.8	320	29
9500E	10.0mm Endotracheal Tube CUFD	10.0	13.5	320	32

PAEDIATRIC

PAEDIATRIC



Length excl. 15 mm connector

Carton Quantity: 10

All tubes are delivered sterile packed, for single use only