

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
<p>Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal</p>	<p>Sales, Order Management and distribution of medical devices including technical service and customer education.</p> <p>Warehousing and distribution of medical devices, including spine loaner operations</p>
<p>Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy</p>	<p>Sales, order management and distribution of medical devices. Including technical service and customer education. Promotion, invoice and order management of medicinal products.</p>
<p>Medtronic Danmark A/S. Arne Jacobsens Allé 17 2300 Kopenhagen Denmark</p>	<p>Sales, order management and distribution of medical devices. Including technical service and customer education</p>
<p>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</p>	<p>Sales, order management and distribution of medical devices. Including technical service and customer education</p>

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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.

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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.

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

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Osterreich 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.

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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 Herzlyia
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