

Cera para Osso

Cera para Hueso / Bone Wax

A Cera para Osso é um hemostático cirúrgico feito a partir da mistura de cera alvejada de abelha, parafina e palmitato de isopropila.

É apresentado em forma de bastão ou tablete, embalados unitariamente e estéreis. A Cera para Osso não apresenta reatividade biológica, sendo bem tolerada pelo tecido. Não deve ser aplicada em locais onde se deseja uma rápida regeneração e fusão óssea.

La Cera para Hueso es un hemostático Quirúrgico fabricado a partir de la mezcla de cera de abeja blanqueada, parafina y palmitato de isopropilo.

Presentado en formato de bastón o tabletas, acondicionados unitariamente y estériles.

La Cera para Hueso no presenta reactividad biológica, siendo bien tolerada por el tejido. No se debe aplicarla en locales en los que se pretende una rápida regeneración y fusión ósea.

Bone Wax is a Surgical haemostatic made from a mixture of whitened beeswax, parafin and isopropil palmitate.

Available in square or cylindrical shapes, sterilized and packed one by one.

Bone Wax does not present biological reactivity and is, well tolerated by tissue.

Not indicated in places where rapid regeneration and bone melt are required.

Cor / Color / Color	Ligeiramente amarelada / Ligeramente amarilleada / Lightly yellowish
Origem / Origen / Origin	Natural / Natural / Natural
Apresentação / Presentación / Box	Unidades com 2,5g embaladas em caixas com 12, 24 ou 36 envelopes Unidades con 2,5g embaladas en cajas con 12, 24 o 36 sobres Units with 2,5g packed in boxes with 12, 24 or 36 units
Esterilização / Esterilización / Sterilization Method	Radiação Gama / Radiación Gama / Radiation
Indicação / Indicación / Indication	Hemostasia mecânica em tecidos ósseos Hemostasia mecánica en tejidos óseos Mechanical haemostasis in bone tissues

Sem Agulha / Sin Aguja / Non Needle	Código / Código / Code	Formato / Formato / Format	Fio Hilo / Stand	Caixa / Caja / Box (env.)
Hemostático Hemostatico Hemostatic	CO1000	Tablete Square Shape	2,5g	12
	COC1000	Bastão Cylinder Shape	2,5g	12



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 077608 0079 Rev. 00

Manufacturer:

Covidien llc

15 Hampshire Street
Mansfield, MA 02048
USA

Product Category(ies): Medical Instruments, Surgical Products
and Hemostatic Materials:

- Surgical Suture Products, Pledgets and Retention Tapes
- Endoscopy Instruments and
Accessories including Lubricant
- Surgical Staple, Clip Products and Accessories
- Manual Surgical Instruments
- Implantable Wound Dressing Materials
- Ultrasonic Surgical Devices and Accessories
- Suction / Irrigation Devices and Accessories
- Arthroscopy Implants, Instruments and Accessories
- Bone Wax
- Temporary Cardiac Pacing Lead
- Powered Stapling Systems

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.:

713164286

Valid from:

2019-09-13

Valid until:

2024-05-26

Date,

2019-09-13

Stefan Preiß
Head of Certification/Notified Body

Page 1 of 2

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT • CERTIFICATE • 認證證書 • CERTIFICADO • CERTIFICAT



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 077608 0079 Rev. 00

Facility(ies):

Covidien Inc
15 Hampshire Street,
Mansfield, MA 02048, USA

4

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

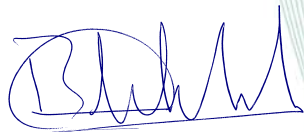
Scope:

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 Copenhagen
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 Österreich 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 OBORISHT
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