

ORDIN DE PLATA NR.: 97

TIP.DOC. 1

DATA EMITERII: 6 august 2020

PLATITI: 3000-00 LEI: Trei Mii lei 00 bani

PLATITOR: (R) S.C. "OXIVI T-MED" S.R.L.

CONTUL DE PLATI/CODUL IBAN MD44ML000000002251729503

CODUL FISCAL : 1007600044280 /

PRESTATORUL PLATITOR BC "Moldindconbank" S.A. fil. "Invest" Chisinau

CODUL BANCII : MOLDM2X329

BENEFICIAR (R) IMSP Institutul de Cardiologie

CONTUL DE PLATI/CODUL IBAN MD98ML000000002251902161

CODUL FISCAL : 1003600150613 /

PRESTATORUL BENEFICIAR BC "Moldindconbank" S.A.

CODUL BANCII : MOLDM2X

DESTINATIA PLATII: "Pentru garantia pentru oferta la licitatie publica nr. oc ds-b: 3wdpl-MD-1596094591975 din 07.08.2020

TIPUL TRANSFERULUI NORMAL/URGENT

L.S.

CODUL TRANZACTIEI: 001

DATA PRIMIRII: 06/08/2020

DATA EXECUTARII:

SEMNRATURILE

EMITENTULUI

CONDUCTOR: Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3DQEHAaCCBIUwggSBMIIDAAADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG: YDVQIQIExFZSXB1YmxyY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxXzFzAV

(semnatura electronica)

CONTABIL-SEF: Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3DQEHAaCCBIUwggSBMIIDAAADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG: SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X: YDVQIQIExFZSXB1YmxyY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxXzFzAV



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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 010244 0055 Rev. 00

Manufacturer:

Belco S.r.l.

Via Camurana, 1
41037 Mirandola (MO)
ITALY

Facility(ies):

Belco S.r.l.
Via Camurana, 1, 41037 Mirandola (MO), ITALY

Product Category(ies): Haemodialysis, apheresis and blood management equipment (including accessories for monitoring of blood pressure, oxygen saturation and heart rate); haemodialysis, apheresis and blood management disposable medical devices like filters and blood lines, plasmafilters and adsorbers, cartridges for haemodialysis, powder concentrates for haemodialysis, liquid concentrates for haemodialysis

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.:

ITA1315239

Valid from:

2019-07-17

Valid until:

2024-05-26

Date,

2019-07-17

Stefan Preiß
Head of Certification/Notified Body

Zertifizierungsvertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：

- 认证所依据标准的有效性
- 此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
 - 生产场地通过定期的监督

認證契約

認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものである。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認證書の有効性に関する原則的な要求事項

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持してい
 - 定期的な工場監査を実施してい

Contrato de certificação

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
 - Auditoria de monitoração realizada regularmente.



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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 010244 0056 Rev. 00

Manufacturer

Bellco S.r.l.

Via Camurana, 1
41037 Mirandola (MO)
ITALY

Facility(ies):

Bellco S.r.l.
Via Camurana, 1, 41037 Mirandola (MO), ITALY

Product

Category(ies):

**Medical devices for extracorporeal treatments:
waste bags, connectors, adaptors, infusion sets,
closure caps and accessories**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

ITA1315239

Valid from:

2019-07-18

Valid until:

2024-05-26

Date,

2019-07-18

Stefan Preiß
Head of Certification/Notified Body

Zertifizierungsvertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：

- 认证所依据标准的有效性
- 此外，对于授权使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
 - 生产场地通过定期的监督

認証契約

認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
 - 定期的な工場監査を実施している

Contrato de certificação

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Requisitos para a validade do certificado (em princípio):

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
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Product Service

EC Certificate

Full Quality Assurance System

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No. G1 010244 0055 Rev. 00

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Belco S.r.l.

Via Camurana, 1
41037 Mirandola (MO)
ITALY

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Requisitos para a validade do certificado (em princípio):

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
 - Auditoria de monitoração realizada regularmente.

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 Henaras, 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
Cépfület 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