ORDIN DE PLATA NR.: 55 TIP.DOC. 1

DATA EMITERII:12 iulie 2021

PLATITI: 4000-00 LEI: Patru Mii lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD44ML000000002251729503
CODUL FISCAL :1007600044280 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R)IMSP Spitalul Clinic Republican "Timofei Mosnea
CONTUL DE PLATI/CODUL IBAN
MD32ML000000002251502448
CODUL FISCAL :1003600150783 /

PRESTATORUL BENEFICIAR
BC"Moldindconbank"S.A.
CODUL BANCII:
:MOLDMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr ocds-b3wdp1-MD-1623402250808 di: n 13072021

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:12/07/2021
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV

(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii

MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV

L.S.

(semnatura electronica)

CONDUCATOR: _____

(semnatura manuala)

CONTABIL-SEF: _____

(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2021.07.20 15:39:06 EEST
Reason: MoldSign Signature
Location: Moldova

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8871** din **05.05.2021**

Denumirea completă: **Societatea Comercială «OXIVIT-MED» S.R.L.**
Denumirea prescurtată: **S.C. «OXIVIT-MED» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
2 Comerţul cu ridicata al parfumurilor şi produselor cosmetice;
3 Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerţ cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerţ cu ridicata;
7 Închirierea altor maşini şi echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociaţi:
1. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 5400.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 05.05.2021.

Specialist coordonator
tel. 022-207-840
Lazari Aliona

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

OXIVITMED
c/f: 1007600044280; adresa: str. Independenței 28-34, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Către Grupul de lucru pentru evaluarea
Procedurii de achiziție Nr. ocds-b3wdp1-MD-1623402250808
din 2 iul 2021, 9:11 - 24 iul 2021, 9:11
din cadrul CAPCS

Declarație

Prin prezenta, SRL „Oxivit-Med”, declara ca,

- Va instala și instrui personalului beneficiarului cu privire la utilizarea echipamentelor livrate, organizate la sediul beneficiarului de către personalul autorizat al furnizorului.
- Termenul de garanție pentru echipamentul oferit nu este mai mic de 24-36 de luni de la data livrării/instalării acestuia.
- Perioada de reacție: jumătate de oră sau mai puțin la telefon și 24 ore sau mai puțin la locul beneficiarului în cazul apariției defecțiunilor tehnice.
- Va organiza inspecțiile planificate / întreținerea profilactică și calibrarea conform programului stabilit și mentenanța dispozitivului medical pe durata perioadei de garanție, efectuat de către un inginer calificat al ofertantului.
- Anul producerii echipamentului nu este mai vechi de anul 2020.
- Va înregistra în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale bunurile contractate pînă la momentul livrării acestora.
- Pînă la momentul livrării va prezenta numărul de înregistrare din Lista producătorilor, conform prevederilor HG 212/2018 privind gestionarea Echipamentelor Electrice si Electronice (EEE).

_____Kojevnikov Dmitrii

L.Ș.

WarmTouch™ Convective Warming System. Maintaining normothermia has never been so easy.

The WarmTouch™ convective warming system provides an easy solution in maintaining normothermia. The WarmTouch™ convective warming unit has an intuitive screen showing the temperature and status of each of the 5 temperature settings. The soft but strong WarmTouch™ blanket range is tailored for most surgical procedures, offering tear resistance, even airflow and patient comfort.

www.covidien.com

COVIDIEN

positive results for life™

Warming with precision, handling with flexibility

A full range of blankets to accommodate every type of patient and procedure.

WARMTOUCH™ FULL BODY MULTI ACCESS BLANKET

Easy access to chest tubes, arteries and pulse checking.

5030810
25/CS

DIMENSIONS
Uninflated
40 in W x 79 in L
102 cm W x 201 cm L

Inflated
33 in W x 74 in L
84 cm W x 188 cm L

WARMTOUCH™ UPPER BODY BLANKET

Dual inlets for added flexibility.

5030870
12/CS

DIMENSIONS
Uninflated
82 in W x 28 in L
208 cm W x 71 cm L

Inflated
72 in W x 24 in L
183 cm W x 61 cm L

WARMTOUCH™ TORSO BLANKET

Large side flaps to tuck underneath the patient. Dual inlets for added flexibility.

5030900
12/CS

DIMENSIONS
Uninflated
52 in W x 40 in L
132 cm W x 102 cm L

Inflated
44.5 in W x 36 in L
113 cm W x 91 cm L

WARMTOUCH™ LOWER BODY BLANKET

Precise, localized warming with adjustable tape positioning.

5030880
12/CS

DIMENSIONS
Uninflated
41 in W x 56 in L
104 cm W x 142 cm L

Inflated
34 in W x 52 in L
86 cm W x 132 cm L

WARMTOUCH™ CARDIAC BLANKET STERILE

Unique design to minimize air distribution at patient's feet.

5030860
12/CS

DIMENSIONS
Uninflated
40 in W x 65 in L
102 cm W x 165 cm L

Inflated
34 in W x 53 in L
86 cm W x 135 cm L

WARMTOUCH™ SURGICAL ACCESS BLANKET STERILE

Sterile access to the surgical site.

5030890
12/CS

DIMENSIONS
Uninflated
40 in W x 79 in L
102 cm W x 201 cm L

Inflated
35 in W x 74 in L
89 cm W x 188 cm L

WARMTOUCH™ PEDIATRIC SURGICAL BLANKET

For over and under body use. Clear plastic head cover to maintain head temperature.

5030850
12/CS

DIMENSIONS
Uninflated
25 in W x 41 in L
63 cm W x 104 cm L

Inflated
22 in W x 35 in L
56 cm W x 89 cm L

WARMTOUCH™ PEDIATRIC FULL BODY BLANKET

Easy access to chest tubes, arteries and pulse checking.

5030840
12/CS

DIMENSIONS
Uninflated
30 in W x 57 in L
76 cm W x 145 cm L

Inflated
27 in W x 49 in L
69 cm W x 124 cm L

WARMTOUCH CONVECTIVE WARMING SYSTEM SPECIFICATIONS

WARMING UNIT AND POWER CORD 5016000A

Weight with Power Cord	5.2kg (11.5 pounds)
Dimensions – hose fully collapsed, nozzle in storage position on unit	60cm x 43cm x 30cm (24 inches x 17 inches x 12 inches)

TRANSPORT CART (OPTIONAL) 5022900

Weight	3.1kg (6.8 pounds)
Height	67.1cm (26.4 inches)
Width	32.3cm (12.7 inches)
Depth	38.6cm (15.2 inches)

ELECTRICAL AND ENVIRONMENTAL REQUIREMENTS

Power Requirements	100 to 240 V AC Max. current at 100 V = 8 A Max. current at 240 V = 5 A
Input Frequency	50/60 Hz ±1 Hz
Fuse (x2)	Littlefuse (mfr.) 0218010; 250 V, 10 A
Temperature	18°C to 28°C (64.4°F to 82.4°F)

PERFORMANCE SPECIFICATIONS

Maximum Contact Surface Temperature	44.1°C (111.4°F)
Average Time for Contact Surface Temperature to Rise from 23°C ±2°C to 37°C	6 minutes
Average Time for Temperature of Air Exiting the Hose to Rise from 23°C ±2°C to 37°C	< 1 minute
Accuracy of Displayed Temperature	±1.0°C (air entering hose)
Automatic Temperature Stepdown (Boost to High Temperature)	After 45 minutes of continuous use, blower will step down from the Boost to High setting.
Thermal Protection Threshold	Thermostat (internal): 49°C to 55°C (120°F to 131°F)
Average Alarm Level	56 dB @ 1 meter

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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6135 Gunbarrel Avenue • Boulder, CO 80301 • 800-635-5267

covidien.com/rms

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positive results for life™

WarmTouch™ Convective Warming System
Maintaining normothermia has never been so easy

WarmTouch™
Convective Warming System

WARMTOUCH™ WARMING BLANKETS

	INTRA-OPERATIVE BLANKETS	PEDIATRIC SURGICAL BLANKET WITH HEADCOVER	FULL BODY BLANKETS
Size Uninflated	Upper Body: 71 cm x 203 cm Lower Body: 99 cm x 137 cm Cardiac: 99 cm x 163 cm Surgical Access: 103 cm x 201 cm Torso: 134 cm x 103 cm	61 cm x 99 cm	Adult: 99 cm x 198 cm Pediatric: 74 cm x 142 cm
	All measurements were taken from the edge welds for consistency		
Construction	2-ply material consisting of polyethylene film inner layer and non-woven outer layers		
Material Characteristics	Tear, puncture and fluid resistant; comfortable to the touch. X-Ray transparent: will not interfere with, or affect X-Rays		
Air Flow	Quilted design allows uniform airflow distribution		
Latex Allergen	None		

WARMTOUCH™ CONVECTIVE WARMING UNIT

Dimensions	60 cm x 43 cm x 30 cm (24 inches x 17 inches x 12 inches)
Weight	5.2 kg (11.5 pounds)
Power Requirements	100 - 240 Volt, max. current at 100V 8A, max current at 240V 5A
Power Cord Length	4.3 m (14 feet)
Average Time for Temperature of Air Exiting the Hose to Rise from 23°C +/- 2°C to 37°C	< 1 minute
Automatic Temperature Stepdown	After 45-minutes of continuous use, blower will step down from the Boost to High setting
Accuracy of Displayed Temperature	+/- 1°C (air entering hose)
Thermal Protection Threshold	Thermostat (internal): 49°C to 55°C (120°F to 131°F)
Blower Operating Temperature Range	18°C - 28°C (64.4°F - 82.4°F)
Over Temperature Alarm Level	63 dB at 3 meters
Protection Against Ingress of Fluids	Ordinary
Air Flow Rate	49,9 CFM - 23.5 L/s
HEPA Filter	Pore size 0.3µ, 99.97% efficient
Product Compliance	IEC 60601-1:2005, EN 60601-1:2006 ANSI/AAMI ES60601-1:2005 CAN/CSA C22.2 No 60601-1:08 IEC 80601-2-35:2009 EN 80601-2-35:2010

REF	DESCRIPTION	BOX QTY
5016000	WarmTouch™ Convective Warming Unit	1
502-2900	WarmTouch™ Cart	1
10092812	HEPA Filter Kit	1
10088307	Nozzle Kit	1
10088303	Hose Kit	1

WarmTouch™ Blankets

Warming Blankets for Intrahospital use

REF	DESCRIPTION	BOX QTY
503-0810	WarmTouch™ Adult Blanket	25
503-0840	WarmTouch™ Pediatric Blanket	12
503-0850	WarmTouch™ Pediatric Surgical Blanket with Headcover	12
503-0860	WarmTouch™ Cardiac Blanket (Sterile)	12
503-0870	WarmTouch™ Upper Body Blanket with Headcover	12
503-0880	WarmTouch™ Lower Body Blanket	12
5030890	WarmTouch™ Surgical Access Blanket (Sterile)	12
5030900	WarmTouch™ Torso Blanket	12

Mon-a-therm™

Temperature Monitoring Sensors

REF	DESCRIPTION	BOX QTY
90050	General Purpose Temperature Probe 9 Ch	50
90044	General Purpose Temperature Probe 12 Ch	50
90049	Oesophageal Stethoscope with Temperature Sensor 9 Ch	25
90041	Oesophageal Stethoscope with Temperature Sensor 12 Ch	25
90042	Oesophageal Stethoscope with Temperature Sensor 18 Ch	25
90043	Oesophageal Stethoscope with Temperature Sensor 24 Ch	25
90045	Skin Temperature Sensor	50
90053T	Foley Catheter with Temperature Sensor 8 Ch	12
90054T	Foley Catheter with Temperature Sensor 10 Ch	12
90055T	Foley Catheter with Temperature Sensor 12 Ch	12
90056T	Foley Catheter with Temperature Sensor 14 Ch	12
90051T	Foley Catheter with Temperature Sensor 16 Ch	12
90052T	Foley Catheter with Temperature Sensor 18 Ch	12

REF	DESCRIPTION	LENGTH
502-0415	Thermistor 400 cable for use with Maquet™* / Siemens™* / Dräger™* monitors	3 m
502-0405	Thermistor 400 cable for use with Maquet™* / Siemens™* / Dräger™* monitors	5 m
502-0411	Thermistor 400 cable for use with Philips™* / Agilent™* / HP™* monitors	3 m
502-0401	Thermistor 400 cable for use with Philips™* / Agilent™* / HP™* monitors	5 m
502-0410	Thermistor 400 cable with 1.4" jack plug, for use with Dräger™*, Marquette™* / GE, Datex-Ohmeda™* / GE™*, Spacelabs™* and Propaq™* monitors	3 m
502-0400	Thermistor 400 cable with 1,4" jack plug, for use with Dräger™*, Marquette™* / GE™*, Datex-Ohmeda™* / GE™*, Spacelabs™* and Propaq™* monitors	5 m

IMPORTANT : Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

This information is intended only for residents of the European Union.

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To contact us,
please visit
www.covidien.com
and select "contact us"

Use scan app to read

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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

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

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

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bei Arzneimitteln und
Medizinprodukten
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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 039709 1304 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies):

- **Autotransfusion Systems and Associated Disposables**
- **Centrifugal Blood Pumps**
- **Bio-Console Drive Units**
- **Flow Monitoring Systems**
- **Bio-Cal Blood Temperature Controller**
- **Temperature Monitoring Systems and Associated Disposables**
- **Blood Monitoring Systems**
- **Cardioplegia Delivery Systems**
- **Disposable Blood Handling Devices used for Open Heart Surgery**
- **Arterial Filters**
- **Oxygenators including Heat Exchangers, with and without Cardiotomy Reservoirs**
- **Cardiotomy Venous Reservoirs**
- **Venous Reservoir Bags**
- **Perfusion Equipment and Disposable Perfusion Devices**
- **Disposable Medical Devices for Drainage Systems**
- **Disposable Medical Devices for use in Extracorporeal Support: Cardioplegia, Cannulae, Catheters, Venting, Suction**
- **Pressure Display System & related accessories of class IIa**
- **Tissue Positioning/Stabilizing Devices**
- **Surgical Site Clearing Devices**
- **Intravascular Shunts**
- **Surgical Retractors**

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.: 72157211

Valid from: 2020-04-29
Valid until: 2024-05-26

Date, 2020-04-29

Christoph Dicks
Head of Certification/Notified Body

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

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

Medtronic

HMS Plus

HEMOSTASIS MANAGEMENT SYSTEM

Believing in the technology... investing in the future

The Trusted Standard, From A Company You Trust

Medtronic, the world's leading medical technology company and a key participant in blood management for more than a decade, introduces new features on the HMS Plus Hemostasis Management System that provide improved ease of use. The HMS Plus System is a reliable and versatile platform used to perform multiple tests for anticoagulation management.

Manufactured by Medtronic, the HMS Plus System combines a trusted standard in precise clot-detection technology with state-of-the-art user enhancements such as: bar code scanner, external data management program and connectivity-ready capabilities.

"Versatility makes HMS PLUS an effective tool for diverse patient management." [1]

HMS Plus
Hemostasis Management System

Why is Hemostasis Management Important for Your Patients?

- Assist in prevention of thrombus formation
- Help preserve clotting factors
- Monitor multiple aspects of anticoagulation

The HMS Plus technology was created with the recognition that the activated clotting time (ACT) is a global or functional test that measures the effect of many variables including:

- Medications
- Heparin anticoagulation
- Temperature
- Dilution

Measuring the ACT, or the degree of anticoagulation, is not always an indication of adequate heparinization or whether an appropriate antithrombotic state has been achieved.

Hemostasis management is achieved with the HMS Plus System and is well suited for use in the operating room, during ECMO, and when Point-of-Care heparin testing is important to successful medical treatment.

Optimized patient treatment using the HMS Plus System includes:	Test Cartridges Used
Measuring actual circulating heparin concentration	Heparin Assay Cartridges
Assessing patient's individual response to heparin	Heparin Dose Response (HDR)
ACT tests	High Range ACT (HR-ACT)

Benefits of the HMS Plus System

Benefits of Improved Hemostasis Management

- Fewer complications associated with excessive blood loss.[1]
- Preservation of the coagulation system, resulting in fewer transfusions.[2]
- Fewer surgical reoperations,[3] thus decreasing associated costs.

"Compared with heparin management with the activated clotting time, heparin concentration-based anticoagulation management during CPB leads to a significant reduction of thrombin generation, fibrinolysis and neutrophil activations, whereas there is no difference on platelet activation" [4]

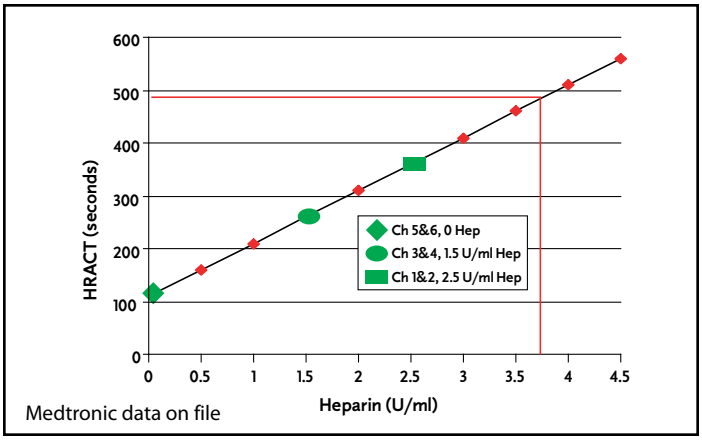
"Retrospective data revealed a marked reduction in the re-exploration rate and post-operative hemorrhage after the introduction of the Hepcon HMS..." [4]

Quantitative Heparin Measurement Versus Activated Clotting Times[2]

Criteria	Control (ACT)	Intervention (HMS)	p Value
Heparin	462 ± 114	612 ± 147	<0.0001
Protamine	0.94 ± .21	0.70 ± 0.64	0.0001
% Transfused	33%	17%	0.005
Closure Time	102 ± 34	92 ± 32	0.02
Platelets	3.7 ± 6.7	1.7 ± 3.6	0.003
FFP	1.4 ± 2.5	0.4 ± 1.3	0.001
Cryo	0.2 ± 1.2	0	0.04
n=254 patients			

Maintenance of patient-specific heparin concentrations, based on heparin concentration measurement during cardiopulmonary bypass led to greater heparin doses and lower doses of protamine relative to heparin dose. Patients in the interventional group received significantly fewer platelets, plasma and cryoprecipitate during the perioperative interval. Patients in the control group required increased hemostatic transfusion during the perioperative period and also required longer closure times.[2]

Heparin Dose Response (HDR) Test

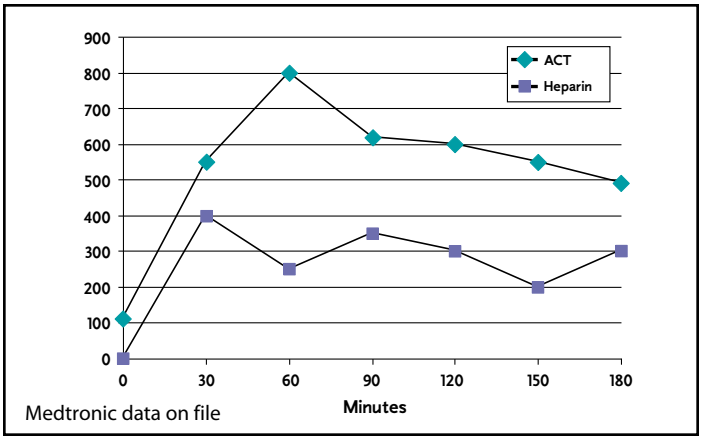


HMS Plus in vitro heparin dose response uses a baseline and two concentrations of heparin to project individual responses to heparin and determine the appropriate heparin dose for each patient.

"Of particular concern is the fact that the ACT has previously been shown to correlate poorly with plasma heparin levels during CPB." [5]

"With typical use of the ACT, the user may obtain values up to 3 times appropriate for the plasma heparin concentration. Potential consequences of this overestimation include the possibility of inadequate intraoperative anticoagulation by heparin, and vastly excessive delivery of protamine, resulting in increased post-operative bleeding." [6]

Heparin Concentration Versus Activated Clotting Times



Illustrates the lack of correlation between heparin concentration and ACT during cardiopulmonary bypass.

Improved Efficiency and Ease of Use

The HMS Plus System dispenses the appropriate volume of blood or control material into each cartridge channel.

Bar Code Scanner

- Saves time by making cartridge and control lot numbers and expiration dates easy to enter
- Efficient entry of patient and user ID

Version 4.0 Software

- Improvements to the user interface allow for more efficient navigation through the menus
- Easy storage and retrieval of results
- Helps maintain the security of patient information and data

Data and QC Management

- Supports the latest requirements for POC testing equipment
- Stores up to 200 patient and 100 QC records
- Offers QC and user lockout options
- Allows purge function of all test records
- Connectivity ready

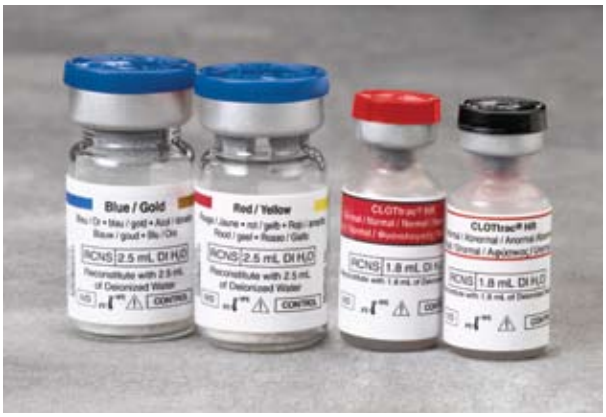
"Importantly, the limits of agreement between measures are very tight at low heparin concentrations, when it is critical not to incorrectly assume adequate anticoagulation. This level of agreement, in conjunction with other beneficial features, such as the rapid turnaround time for results, individualized heparin-dosing protocols and more accurate protamine dosing, makes the Hepcon (HMS) a useful tool in the monitoring of anticoagulation during CPB." [5]

External Data Management (EDM)

- Stand alone software
- Easier download of data
- Documentation for billing and reimbursement
- QC and patient data management including preformatted reports

Quality Control

Lyophilized controls are available to verify instrument and cartridge function and to meet regulatory guidelines for testing.



The HEPtrac™ Electronic Quality Control provides a multi-level quality check to make quality control easier and faster to perform.

"The rapid disappearance of heparin from the circulation may in part be due to distribution to another body compartment and also possibly to heparin binding to the artificial surfaces. This decline in heparin levels was not detected by either ACT technique… the Hepcon (HMS) dropped accordingly." [5]

Ordering Information

HMS Plus Test Cartridges and Liquid Controls

Disposable cartridges undergo strict manufacturing standards and quality control to provide accurate, dependable performance. Cartridge room temperature and/or refrigerated shelf life are stamped on each box.

Heparin Assay Cartridges and Controls

Cartridges: Each box contains 9 cartridges with syringes and blunt tip needles				Controls: Each box contains 10 vials of control and deionized water	
Catalog #	**Description**	**# of Channels**	**Heparin Level**	**Control Catalog #**	**Description - (10 vials of control and 10 vials of deionized water for reconstitution)**
304-01POR	Red	4	0.0-0.9 mg/kg	306-01POR	Red/Yellow
304-02POR	Yellow	4	0.0-1.5 mg/kg		
304-03POR	Tan	4	1.5-3.0 mg/kg	306-02POR	Tan/Silver
304-04POR	Silver	4	2.0-3.5 mg/kg		
304-05POR	Blue	4	2.5-4.0 mg/kg	306-03POR	Blue/Gold
304-06POR	Green	4	3.5-5.0 mg/kg	306-04POR	Green/White
304-07POR	Orange	6	0.0-2.5 mg/kg	306-05POR	Orange
304-08POR	Gold	6	1.5-4.0 mg/kg	306-03POR	Blue/Gold
304-09POR	White	6	2.5-5.0 mg/kg	306-04POR	Green/White
304-10POR	Purple	4	4.5-6.0 mg/kg	306-09POR	Purple/Black
304-11POR	Black	6	3.5-6.0 mg/kg		

Heparin Dose Response Cartridge

Cartridges: Each box contains 9 cartridges, syringes, and blunt tip needles		
Catalog #	**Description**	**# of Channels**
304-20POR	HDR	6

High Range ACT

Cartridges: Each box contains 18 cartridges and 9 syringes, and blunt tip needles			Control: Each box contains 15 vials of control and deionized water	
Catalog #	**Description**	**# of Channels**	**Control Catalog #**	**Description**
304-30	HRACT	2	550-07	CLOTtrac HR Coagulation Control
			550-08	CLOTtrac HR Abnormal Coagulation Control
			550-13	CLOTtrac HR Control Pak Coagulation Control (1 box each of 550-07 and 550-08)

HMS Plus Instruments

Each instrument includes an internal printer, one-year warranty, operating manual, and case analysis pad.

Catalog #	Description		
30514	HMS PLUS	100-120 volt	
30522	HMS PLUS	200-240 volt	English
30515	HMS PLUS	200-240 volt	German
30517	HMS PLUS	200-240 volt	French
30518	HMS PLUS	200-240 volt	Italian
30524	HMS PLUS	200-240 volt	Spanish
30527	HMS PLUS	200-240 volt	Dutch

HEPline Kit

Kit contains 5 tubes of increasing amounts of heparin concentrations designed to give final concentrations of 1, 2, 3, 4, and 5 U/ml when fresh whole blood is added to a final volume of 5 ml.

Catalog #	Description
313-50	HEPline Kit

Accessories

Catalog #	Description	Quantity
HMSPLUSSC	Bar Code Scanner	1
HMSPUSSCRS	Bar Code Scanner - European Union	1
HMSPLUSSCYY	Bar Code Scanner - Japan	1
HMSPLUSEDM	External Data Manager	1
31351	Electronic Quality Control	1
300-01	3cc Monoject Syringes	100 per Box
300-02	Blunt Needles, 1-7/16", 19 GA	100 per Box
300-04	Thermal Printer Paper	5 Rolls per Box
300-05	HMS Case Analysis Pad	50 Sheets per Pad
300-10	Temperature Verification Cartridge	1
313-18	QA Records Packet	1
31506	Salvage Reservoir Cups	100 per Box
30032	HMS PLUS Custom Cart	1

Manuals

Manuals can be ordered through the CardioVascular Service Department.

Part Number	Description
86506001	Operator's Manual

Support Information

Customer Support

Medtronic is proud of our commitment to customer-focused quality. We have dedicated team members in sales, product services and technical support to assist you and help you identify your product needs.

Customer Service

For ordering information on instruments, test cartridges and controls, contact your Customer Service Representative or your local Medtronic Product Sales Representative.

CardioVascular Service

Field-based service representatives provide on-site instrument service for routine maintenance and ongoing support. Annual service contracts are available. To contact your local Field Service Representative, call 800-433-4311.

Technical or Regulatory Information

For questions on the use of our products or on hospital and laboratory regulations regarding their use, call 800-328-3320.

Caution:

Federal law (USA) restricts this device to sale by or on the order of a physician.

For more information contact your local Medtronic Sales Representative or call Customer Service toll-free at 1-800-328-1357.

Warnings: Proper Instrument and Cartridge Use

The HMS Plus instrument and cartridges must only be used in the manner and purpose for which they are intended. Instructions for proper use are included in the manual and in the cartridge package inserts. Read all warnings, precautions and Instructions for Use carefully prior to use.

System Specifications

Physical Dimensions:

Height: 40 cm (15.75") Depth: 38 cm (15.0")
Width: 33 cm (13.0") Weight: 15.47 kg (34.1 lbs.)
Serial Data Port: 19200 baud, 8 data bits, 1 stop bit, no parity

Environmental:

- Operating temperature: 14°C to 32°C (57°F to 90°F)
- Storage temperature: 0°C to 49°C (32°F to 120°F)
- Operating humidity: 10% to 90%, noncondensing
- Storage humidity: 5% to 90%, noncondensing

Power:

- Voltage: 100 - 240 V~ Single Phase
- Frequency: 50 - 60 Hz
- Maximum current: 1.2/0.6 A (100 - 120/200 - 240)

References

1. Hill AG, et al. More precise heparin and protamine management during cardiopulmonary bypass. Proceedings of the American Academy of Cardiovascular Perfusion. 1990;12-16.
2. Despotis GJ, et al. The impact of heparin concentration and activated clotting time monitoring on blood conservation. J Thoracic Cardiovascular Surg. 1995;110:46-54.
3. Bowie JE, et al. Automated management of heparin anticoagulation in cardiovascular surgery. Proceedings of the American Academy of Cardiovascular Perfusion. 1985;6:1-5.
4. Koster A, et al. Hemostatic activation and inflammatory response during cardiopulmonary bypass. Anesthesiology. 2002; 97: 837-841.
5. Raymond PD, et al. Heparin monitoring during cardiac surgery. Part 1: validation of whole-blood heparin concentration and activated clotting time. Perfusion. 2003; 18: 269-276.
6. Raymond PD, et al. Heparin monitoring during cardiac surgery. Part 2: calculating the overestimation of heparin by the activated clotting time. Perfusion. 2003; 18: 277-281.

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LifeLine
CardioVascular Technical Support
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E-mail: rs.cstechsupport@medtronic.com

Medtronic

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 039709 1211 Rev. 00

Holder of Certificate: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

Certification Mark:

Scope of Certificate:

Design, Development, Manufacturing, Distribution and Service of High-Frequency Electrosurgical Generators and Hand Pieces, Near-Patient Coagulation Analyzer, Coagulation and QC Cartridges, Autotransfusion System & Associated Disposables, Centrifugal Blood Pumps (Coated & Uncoated), Bio Console Drive Units, Flow Monitoring Systems (Coated & Uncoated), Bio Cal Blood Temp. Controller, Temp Monitoring Systems & Associated Disposables, Blood Monitoring Systems (e.g. TMCs) (Coated & Uncoated), Cardioplegia Delivery Systems (Coated & Uncoated) Disposable Blood Handling Devices Used for Open Heart Surgery (Coated & Uncoated) (e.g. Tubing, Connectors), Arterial Filters (Coated & Uncoated), Oxygenerators Including Heat Exchangers w & w/o Cardiotomy Venous Reservoirs (Coated & Uncoated), Cardiotomy Venous Reservoirs (Coated & Uncoated), Disposable Medical Devices for Drainage Systems, Perfusion Related Equipment, Cannulae (Coated & Uncoated), Venous Reservoir Bags (Coated & Uncoated), Intravascular Catheters, Tissue Positioning/Stabilizing Devices, Surgical Retractors and Accessories, Surgical Site Clearing Devices, Intravascular Shunts, Devices for Anastomotic and Tissue/Prosthetic Material Approximation and Removal, Disposable Medical Devices Used in Cardiopulmonary Bypass Procedures, and Service of Cryoablation Console.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72138198

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-03-29

Stefan Preiß

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 039709 1211 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Medtronic Perfusion Systems
7611 Northland Drive, Minneapolis, MN 55428, USA

Medtronic Perfusion Systems
18501 East Plaza Drive, Parker CO 80134-9061, USA

Parameters:./.

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

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

MGMT. SYS. RvA C 589

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 Cornella 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 Milennium 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 Herzlya 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.

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Medtronic Ireland Limited Block 3090-3094Lake 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