```
-----------------------------------------------------------------:
ORDIN DE PLATA NR.: 17                               TIP.DOC. 1 :
                                DATA EMITERII:23 februarie 2021 :
================================================================:
PLATITI: 125000-00        LEI: Una Suta Douazeci si Cinci Mii   :
 lei 00 bani                                                    :
                                                                :
================================================================:
PLATITOR:  (R) S.C. "OXIVI    CONTUL DE PLATI/CODUL IBAN        :
T-MED" S.R.L.                 MD44ML000000002251729503          :
                              CODUL FISCAL :1007600044280  /    :
                                                                :
                                                                :
================================================================:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau        :MOLDMD2X329:
================================================================:
BENEFICIAR (R) Centrul pen    CONTUL DE PLATI/CODUL IBAN        :
tru Achizi?ii Publice Central MD23TRPCCC518430B01859AA          :
izate in Sanatate             CODUL FISCAL :1016601000212 /     :
                                                                :
                                                                :
================================================================:
PRESTATORUL BENEFICIAR                              CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat          :TREZMD2X   :
================================================================:
DESTINATIA PLATII:/P102/125000,00 Pentru:   TIPUL TRANSFERULUI  :
 garantia pentru oferta la procedura de :      NORMAL/URGENT  :N:
achizi?ie publica CAPCS INN nr.  ocds-b3:                       :
wdp1-MD-1611040117724 din 24.02.2021    :                       :
                                        :                       :
                                        :              L.S.     :
========================================: ___________           :
                  CODUL TRANZACTIEI:101: ___________            :
           DATA PRIMIRII:23/02/2021      : SEMNATURILE           :
         DATA EXECUTARII:23/02/2021 0:00:00: EMITENTULUI         :
                                        :-----------------------:
CONDUCATOR:Web Kojevnikov Dmitrii                               :
MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
________________________________________________________________:
                        (semnatura electronica)                 :
CONTABIL-SEF:Web Kojevnikov Dmitrii                             :
MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
________________________________________________________________:
L.S.                    (semnatura electronica)                 :
CONDUCATOR:            _________________________________________:
                        (semnatura manuala)                     :
CONTABIL-SEF:          _________________________________________:
________________        (semnatura manuala)                     :
SEMNATURA PRESTATORUL       L.S.                                :
                                        :-----------------------:
MOTIVUL REFUZULUI                       :      L.S.             :
-----------------------------------------------------------------:
SEMNATURA BANCII :
```

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iXJdKwu1MSuJZ2cX7bRR993Z+s2ZXMHf2gPuJUqkQfWoSNRZLME+9prYElcSpehBD
vEGOXRdL4qekMKMlQ==

Digitally signed by Kojevnikov Dmitrii
Date: 2021.02.23 17:13:45 EET
Reason: MoldSign Signature
Location: Moldova

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

Funcţia, numele, prenumele persoanei care a eliberat certificatul

semnătura

MD 0067985

L.Ş.

REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII **Nr.** 044647

Denumirea autorității de licențiere	**Camera de Licențiere**
Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență	**Societatea Comercială „OXIVIT-MED" S.R.L.** mun.Chișinău, bd. Decebal, 82, ap. 90
Data și numărul certificatului de înregistrare de stat a titularului de licență	30.07.2007 MD 0067985
Numărul de înregistrare a întreprinderii sau IDNO	1007600044280
Codul fiscal	
Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența	*** Importul și comercializarea dispozitivelor medicale ***
Data eliberării licenței	15 octombrie 2012
Valabilă pînă la Prelungită pînă la: 15.10.2022	15 octombrie 2017

Semnătura conducătorului autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

MOBIAS BANCA

Nr. 12101-504

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.Ş.

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

„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **71** din **05.01.2016**

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 și codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;
2 Comerțul cu ridicata al parfumurilor și produselor cosmetice;
3 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerț cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerț cu ridicata;
7 Închirierea altor mașini și echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociați:
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 și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 05.01.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA * CAMERA ÎNREGISTRĂRII DE STAT Î.S. * 1004600077171 * 101 *

AA6 * EA * 0346843EA

c/f: 10037600044280; 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

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	09723015012362

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. № A2102230 **din** от 16.02.2021

1. Destinația / Назначение

Agenția Achiziții Publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	**Codul fiscal / Numărul de identificare** Фискальный код / Идентификационный номер
S.C. OXIVIT-MED S.R.L.	1007600044280
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** Код - Наименование населенного пункта
Decebal bd. nr.82 of.90	0110-SEC.BOTANICA

3. 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: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 03.03.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Sef DDF Botanica		Ana STOICOV
Funcția Должность	**Semnătura** Подпись	**Numele și prenumele** Фамилия и имя

L.Ș. М.П.

Executor: L. Crutco
Numele și prenumele Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 16.02.2021 ora 13:14:10 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)

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
licitației publice Nr. 21034459 din 24.02.2021
din cadrul CAPCS

Declarație

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

- Termenul de valabilitate restant (la momentul livrării) va constitui 80% din termenul total al produsului, dar nu mai mic de 12 luni.
- Pentru produsele noi sau necunoscute pentru medici, vor fi prezentate mostre de către potențialii cîștigători în termen de 5 zile de la solicitare
- se obligă să înregistreze bunul contractat, la AMDM, până la momentul livrării acestuia.

Kojevnikov Dmitrii _____

By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 596357**

Issued To: **Neuravi Limited**
Block 3
Ballybrit Business Park
Galway
Ireland

In respect of:

EmboTrap Revascularization System

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-10-03** Date: **2020-05-27** Expiry Date: **2023-10-02**

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EC Design-Examination Certificate

Supplementary Information to CE 596357

Issued To:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

EmboTrap Revascularization System

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ET-007	EMBOTRAP	5mm x 21mm	The EmboTrap® Revascularization Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels of diameter 1.5mm to 5mm, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III

First Issued: **2013-10-03** Date: **2020-05-27** Expiry Date: **2023-10-02**

EC Design-Examination Certificate

Supplementary Information to CE 596357

Issued To:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ET-007-521	EMBOTRAP II	5mm x 21mm	EmboTrap™ II Revascularization Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels of diameter 1.5mm to 5mm, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III
ET-007-533	EMBOTRAP II	5mm x 33mm		Class III

First Issued: **2013-10-03** Date: **2020-05-27** Expiry Date: **2023-10-02**

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Supplementary Information to CE 596357

Issued To:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ET307522	EMBOTRAP III	5mm x 22mm	The EMBOTRAP™ III Revascularization Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III
ET307537	EMBOTRAP III	5mm x 37mm		Class III
ET307645	EMBOTRAP III	6.5mm x 45mm		Class III

First Issued: **2013-10-03** Date: **2020-05-27** Expiry Date: **2023-10-02**

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EC Design-Examination Certificate

Supplementary Information to CE 596357

Issued To:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GCE4528	CERENOVUS NIMBUS	4.5mm x 28mm	The CERENOVUS NIMBUS Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels of diameter 1.5 mm to 5.0 mm, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III

First Issued: **2013-10-03** Date: **2020-05-27** Expiry Date: **2023-10-02**

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EC Design-Examination Certificate

Supplementary Information to CE 596357

Issued To:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Certificate History

Date	Reference Number	Action
03 October 2013	10140525	First Issue.
23 February 2016	10161054	Change in Legal Manufacturer Address following relocation of Head Office.
06 May 2016	10161991	Shelf life extension of EmboTrap product to 3 years.
05 July 2016	10163200	DuPont Tyvek packaging change and the addition of the EmboTrap II products to the range.
29 May 2018	8924656	Supplement review covering the UV bond process change and update to the in-process colour acceptance criteria.
04 June 2018	8918628	Introduction of a variable ETO sterilisation load (1-3 pallets) for Embotrap Devices.
20 August 2018	8939388	Certificate Renewal.
13 November 2018	9641867	Addition of the Geometric Clot Extractor (GCE) to the product range.
27 February 2019	8154450	Traceable to NB 0086.

First Issued: **2013-10-03** Date: **2020-05-27** Expiry Date: **2023-10-02**

EC Design-Examination Certificate

Supplementary Information to CE 596357

Issued To:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Certificate History

Date	Reference Number	Action
Current	3043227	Addition of product codes ET307522, ET307537, and ET307645. Product name change from "Geometric Clot Extractor" to "CERENOVUS NIMBUS". Addition of products table in supplementary information section.

First Issued: **2013-10-03** Date: **2020-05-27** Expiry Date: **2023-10-02**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 84868**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

In respect of:

The design, development and manufacture of sterile Endoluminal Stent Grafts, sterile Securement Devices and Delivery Systems for Endovascular Indications, sterile Vascular Introducer Sheaths, sterile Stent Graft Balloon Catheters, sterile Coronary Stents and Delivery Systems, Sterile Intravascular Catheters and sterile/non-sterile Catheter Systems for Renal Denervation.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Attain Clarity Venogram Balloon Catheter	See CE 593123
N/A	Driver Sprint Rapid Exchange Coronary Stent System	See CE 545439
N/A	Endeavor Resolute Zotarolimus-Eluting Coronary Stent System Resolute Integrity Zotarolimus-Eluting Coronary Stent System	See CE 514336
N/A	Endeavor Sprint Zotarolimus-Eluting RX Coronary Stent System	See CE 86406
N/A	Endurant™ Stent Graft System Endurant™ II Stent Graft System Endurant™ IIs Stent Graft System	See CE 559659
N/A	Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 622066
N/A	Heli-FX™ EndoAnchor™ Systems	See CE 669930
N/A	IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)	See CE 570280

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	IN.PACT Falcon (Paclitaxel-eluting PTCA Balloon Catheter)	See CE 570282
N/A	IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)	See CE 570281
N/A	Integrity Rapid Exchange Coronary Stent System	See CE 91271
N/A	Micra™ Introducer Sheath with Hydrophilic Coating	See CE 599898
N/A	NC Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 612356
N/A	NC Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630635
N/A	NC Sprinter Rapid Exchange Balloon Dilatation Catheter	See CE 506473
N/A	Reliant Stent Graft Balloon Catheter	See CE 635936
N/A	Resolute Onyx Zotarolimus-Eluting Coronary Stent System	See CE 618060
N/A	Sentrant Introducer Sheath with Hydrophilic Coating	See CE 595294
N/A	Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630580
N/A	Sprinter Legend OTW Balloon Dilatation Catheter	See CE 547584

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Sprinter Legend RX Balloon Dilatation Catheter	See CE 525652
N/A	Sprinter Over-the-Wire Balloon Dilatation Catheter	See CE 92065
N/A	Telescope Guide Extension Catheter	See CE 701802
N/A	Valiant Navion™ Thoracic Stent Graft System	See CE 702496
N/A	Valiant Thoracic Stent Graft with the Captivia Delivery System	See CE 554030

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Class IIb products under the scope of CE 84868		
GMDN #	**Device or Generic Device Group**	**Intended Purpose per IFU**
58893 (Catheter) 35156 (Generator)	Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter & Symplicity G3™ Renal Denervation RF Generator	The Symplicity G3™ Renal Denervation RF Generator when used with the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter is intended to deliver low-level radio frequency (RF) energy through the wall of the renal artery to denervate the human kidney.

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Class IIb products under the scope of CE 84868		
GMDN #	**Device or Generic Device Group**	**Intended Purpose per IFU**
46777	Talent Endoluminal Occluder System	The Talent Endoluminal Occluder System is intended for endoluminal occlusion of the contralateral iliac artery in cases where an abdominal aortic aneurysm is treated with an aorto-uni-iliac stent graft and subsequent femoral-to-femoral bypass procedure

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Class IIa products under the scope of CE 84868		
NBOG code	**Device or Generic Device Group**	**Intended Purpose per IFU**
MD0106	Confida™ Expandable Sheath	The Confida™ Expandable Sheath is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters or devices introduced into the femoral iliac arteries.

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Invatec S.p.A. Via Martiri della Libertà 7 25030 Roncadelle (BS) Italy	**Manufacture**
Medistri SA Rte de L'Industrie 96 1564 Domdidier Switzerland	**ETO Sterilization**
Medtronic B.V. / E.O.C. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	**EU Representative**
Medtronic CoreValve LLC 1851 E. Deere Ave Santa Ana, CA 92705 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**Design** **EU Representative** **Manufacture**
Medtronic Mexico EG Carret. Int. Km. 1969 Guad-Nogales Km. 2 85340 Empalme Sonora Mexico	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Manufacture**
Medtronic Vascular 3576 Unocal Place Santa Rosa California 95403 USA	**Design**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Phoenix DeVentures, Inc. 18655 Madrone Parkway Suite 180 Morgan Hill California 95037 USA	**Manufacture**
Plexus Corp. Pinnacle Hill Kelso TD5 8XX United Kingdom	**Manufacture**
Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone Phase II, 11900 Bayan Lepas Penang Malaysia	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
SSP-SiMatrix, Inc. 1131 North US Highway 93 Victor Montana 59875 USA	**Manufacture**
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	**ETO Sterilization**
Surmodics, Inc. 9924 West 74th Street Eden Prairie Minnesota 55344 USA	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	**E Beam Sterilization** **ETO Sterilization**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**E Beam Sterilization**
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **2019-08-22**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
24 August 2004		First Issued.
15 November 2004		Transfer of the following certificates from NSAI:- Q252.322, Q252.407, Q252.426, Q252.427, Q252.428, Q252.467, Q252.480, Q252.587, and Q252.611 D252.587 and D252.407, plus incorporation of Medtronic Vascular Ireland as a subcontract manufacturer.
02 December 2004		Carotid and Coronary Stents and Delivery Systems added to the scope (transfer) Medtronic Mexico (manufacture), and Titan Scan Systems, Nutec Corporation, Sterigenics (Queensbury), Steris Corporation-Isomedix Services (Sandy), Rocialle in Health (Mid Glamorgan UK), and EBIS Iotron added as sub-contract sterilizers.
21 December 2004		PTCA Balloon Dilatation Catheters added to the range of products manufactured (transferred from another Notified Body) and Isotron Ireland Ltd added as sub-contract sterilization site.
19 August 2005		Sterilization sub-contractor name change from Titan Scan Systems to Beam One.
03 April 2006		Addition of Sterigenics UK Ltd, as sterilization sub-contractor.
07 August 2006		Addition of AD)MEDES Schuessler GmbH as a sub-contractor for manufacture.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **2019-08-22**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
11 January 2008	7149866	Subcontractor name change from EBIS Isotron, Harwell to Isotron Harwell. Addition of Isotron plc, Daventry as a subcontractor for E beam sterilization.
03 October 2008	7279045	Addition of Medtronic Mexico EG, Empalme as a subcontractor for manufacture.
14 April 2009	7341499	Correction of the legal name of the Medtronic Mexico facility and postcode for the Isotron PLC, Daventry facility. Addition of the activity of EU Representative for Medtronic Ireland.
13 August 2009	7432878	Certificate renewal. Addition of Accellant Inc as a manufacturing subcontractor, amendment to company name for Isotron PLC, Daventry, and Steris Corporation, Sandy, Utah. Change to address for the subcontractor, Nutek Corporation. Addition of E Beam Sterilization for Isotron Ireland. Rewording of scope for clarification purposes only.
29 July 2010	7546410	Added C.R. Bard, Inc. to the list of significant subcontractors for manufacturing. Extended the scope to include guidewires.
12 October 2011	7730209	Extension to scope to include Catheter Systems for Renal Denervation. Removal of Carotid Stents and Delivery Systems from the scope. Minor amendments to Isotron Daventry and Isotron Tullamore's addresses.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **2019-08-22**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
26 January 2012	7792125	Amendment to significant subcontractors to reflect Isotron's name change to Synergy Health and removal of Isotron Harwell.
25 May 2012	7842435	Amendment to the address format and zip code for the significant subcontractor Medtronic Mexico (Tijuana).
19 December 2012	7915649	Addition of Medtronic B.V. The Netherlands for EU Representative Activities.
22 January 2013	7945194	Extension to scope to include Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems.
28 February 2013	7960715	Addition of Invatec Technology Center GmbH to the list of significant subcontractors for manufacturing activities.
28 March 2013	7943883	Extension to Scope to include Vascular Introducer Sheaths and the addition of Teleflex Medical for manufacturing activities.
16 December 2013	8082854	Addition of Plexus Manufacturing Sdn Bhd, Malaysia and Plexus Corp, UK to the list of significant subcontractors for manufacturing activities.
13 July 2014	8154862	Certificate Renewal. Various updates and changes to the list of significant subcontractors. Correction of the reference number for the reissue dated 19th December 2012 on the certificate history page.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **2019-08-22**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
31 July 2015	8350802	Addition of SSP SiMATrix Inc. as balloon supplier for the Attain Clarity.
01 July 2016	8545838	C. R. Bard, Inc., Medtronic Ardian LLC, Nutek Corporation, Sterigenics NY and Apical Instruments Inc. were removed from the list of significant subcontractors.
09 October 2017	8696759	Certificate scope updated to add the design, development and manufacture of securement devices for endovascular indications.
01 May 2018	8895951	Specify devices covered in this certificate are sterile/non-sterile. Move 'sterile Vascular Introducer Sheaths' up in the scope after securement devices. Remove 'Renal Stents and Delivery Systems' and 'guidewires for diagnostic or interventional procedures' from scope. Correction to certificate history entry #2 from '2014' to '2004'.
06 March 2019	8786554	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **2019-08-22**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
Current	9736517	Certificate Renewal. Added product table per MDP4500 Appendix A. Clarified addresses of subcontractors to exactly align with their ISO certificate name and address. Remove "sterile Iliac Stents and Delivery Systems, sterile Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems" from scope as the Complete SE product (iliac and vascular indications) is no longer manufactured nor in the distribution chain. Remove Assurant Cobalt product (iliac product scope) it is no longer manufactured and the last product builds expired in April 2019. Remove subcontractors – Admedes Schuessler GmbH, Germany, Flextronics Medical, Austria, Sterigenics, Corona, CA, Synergy Health, Ireland related to removed products above. Add subcontractors - Phoenix DeVentures, CA, Sterigenics, Los Angeles, CA, SurModics, MN and Medtronic, Santa Ana, CA related to new Class IIa product Confida Expandable Sheath.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 1259 Rev. 00

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis MN 55432
USA

EC-Representative: **Medtronic Ireland**
Parkmore Business Park West, Galway, Ireland, IRELAND

Product Category(ies): **Temporary Occlusion and Aspiration System; Angioplasty and Angiography Products (Angiography Catheters, Guiding Catheters, Diagnostic Catheters, Guidewires, Introducers)**

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.: 72146095

Valid from: 2019-07-23
Valid until: 2024-05-26

Date, 2019-07-23

Stefan Preiß
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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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 039709 1259 Rev. 00

Facility(ies):

Medtronic Vascular
37A Cherry Hill Drive, Danvers MA 01923, USA

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

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

Legal Manufacturer Name:	Neuravi Limited
Address:	Neuravi Limited Block 3, Ballybrit Business Park Galway, Ireland

Product Name	EmboTrap
Product Classification	III
Classification Rule	Rule 6
Conformity Pathway	Annex II
Name and ID of notified body	BSI 2797
CE Certificate Number	CE 596356 – Full Quality Assurance
Design Certificate Number	CE 596357

Neuravi declares the above documented product(s) issued under the responsibility of the manufacturer meets the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC.
This declaration authorizes Neuravi to affix the CE-marking to the products listed herein.

Niall Fox

Digitally signed by Niall Fox
DN: cn=Niall Fox, o=Cerenovus, ou, email=nfox5@its.jnj.com, c=IE
Reason: I am approving this document.
Date: 2020.06.17 18:01:22 +01'00'
Adobe Reader version: 11.0.10

17-June-2020

Date of Approval

Niall Fox
Associate Director Regulatory Affairs

Location of Approval: Galway, Ireland

CE Mark Implementation Details

	Product Name	Product Code*	Date CE Mark Affixed (Date it is added to labels and used on product)
Neuravi Revascularization Devices	EmboTrap	ET-007	Immediate, 15th October 2013
	EmboTrap II	ET-007-533 ET-007-521	Immediate, 14th July 2016
	CERENOVUS NIMBUS	GCE4528	Immediate, 13th November 2018
	EMBOTRAP III	ET307522 ET307537 ET307645	Immediate, 27th May 2020

Approvals		
Print Name & Role	**Signature**	**Date**
Niall Fox *Associate Director Regulatory Affairs*	Niall Fox Digitally signed by Niall Fox DN: cn=Niall Fox, o=Cerenovus, ou, email=nfox5@its.jnj.com, c=IE Reason: I am approving this document Date: 2020.06.17 17:59:31 +01'00' Adobe Reader version: 11.0.10	17-June-2020

*The product code represents the device identifier component of the unique device identifier (UDI). The production identifier(s) used in the UDI will vary with each production lot (e.g. lot number).

Declaration Revision History:

DCN #	Revision #	Brief description Changes
152	01	Initial issue of DOC for EmboTrap
377	02	Update of the DOC to correct typographical error in the part number
429	03	Update of the DOC to include the new address for the legal manufacturer
489	04	Update to the DOC to include the new EmboTrap II product codes
1046	05	Update to the DOC to align with updates to the template RA001.F02
1179	06	Update to the DOC to include the new EmboTrap GCE product codes
1285	07	Update to the DOC to reference new notified body number for BSI Netherlands

1787	08	Update to include the new EMBOTRAP III product codes and update to include product name change from Geometric Clot Extractor (GCE) to CERENOVUS NIMBUS.

Gareth Clarke

Digitally signed by Gareth Clarke
DN: c=US, o=JNJ, ou=Subscribers, cn=Gareth Clarke, 0.9.2342.19200300.100.1.1=1528 10030
Reason: I am certifying this document
Date: 2020.06.17 17:56:33 +01'00'
Adobe Acrobat version: 11.0.10

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Holds Certificate Number: **MD 593929**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development and manufacture of sterile revascularisation devices for the treatment of stroke.

Previous certificate expired June 2, 2019
Recertification audit ended May 13, 2019

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-06-03
Latest Revision Date: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2022-06-02

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UKAS MANAGEMENT SYSTEMS 003

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

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 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 Kopenhagen 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 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.

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 Osterreich GmbH Milennium 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 Cépület 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 Lentäjäntie 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