ORDIN DE PLATA NR.: 72 TIP.DOC. 1

DATA EMITERII:joi, 30 mai 2024

PLATITI: 1000-00 LEI: Una Mie lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD44ML0000000022517295O3
CODUL FISCAL :1007600044280 /

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

BENEFICIAR (R)IMSP Institutul de Cardiologie
CONTUL DE PLATI/CODUL IBAN
MD98ML0000000022519021 61
CODUL FISCAL :1003600150613 /

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

DESTINATIA PLATII:Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1716269896400 din 31.05.2024

TIPUL TRANSFERULUI NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:30/05/2024

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii

MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBH0wggR5MIIDYaADAgECAhNHAADml2rTzDkidh/bAAAAAOaXMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIzMDMxNjE1MjYyMloXDTI2MDMxNjE1MzYyMlowgbAxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTETMBEGA1UEChMKT3hp

(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii

MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBH0wggR5MIIDYaADAgECAhNHAADml2rTzDkidh/bAAAAAOaXMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIzMDMxNjE1MjYyMloXDTI2MDMxNjE1MzYyMlowgbAxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTETMBEGA1UEChMKT3hp

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: 2024.05.30 14:59:37 EEST
Reason: MoldSign Signature
Location: Moldova

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **0945280**

Din От **27.05.2024 09:45**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1007600044280

Denumirea
Наименование

Societatea Comercială OXIVIT-MED S.R.L.

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **11.06.2024 09:45**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **27.05.2024 09:45**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

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

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

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 (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
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,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

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: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

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

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

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077608 0079 Rev. 00

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

Product Category(ies):

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

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713164286

Valid from: 2019-09-13
Valid until: 2024-05-26

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

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

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

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 077608 0079 Rev. 00

Facility(ies):

Covidien llc
15 Hampshire Street,
Mansfield, MA 02048, 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

TÜV®

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2008481DE24

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands

For the product

Implantable Pacemaker Vitatron G-Series

Documents, that form the basis of this certificate:

Certification Notice 2007317CN, initially dated 15 December 2000
Addendum, initially dated 16 December 2009

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 2 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 2 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 January 2024
Issued for the first time: 16 December 2009
Reissued: 1 January 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

G Adams
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2008481DE24

EC DESIGN-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Implantable Pacemaker Vitatron G-Series

Issued to:

Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands

This certificate covers the following product(s):

- Vitatron G70 DR, model G70 A1
- Vitatron G20 SR, model G20 A1
- Vitatron MRI™ SureScan™, G70 DR, model G70A2
- Vitatron MRI™ SureScan™, G20 SR, model G20A2

Initial date: 16 December 2009

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

G Adams
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

vitatron	Document Title: *DoC0023*	Document Number: DoC0023
EC DECLARATION OF CONFORMITY	*G-Series A2 models G20A2, G70A2 and Application Software VSF21*	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	22 May 2017
Corrected EC certificate reference from 2008481DE33 to 2008481DE24 for the pulse generators	3.0	24 May 2017
Updated approver role Updated Applicable Standards Date of Issue of EN 45502-1, EN ISO 11607-1, EN 60601-1-6, EN 62304 and Standard Number and Date of Issue of EN 62366-1 ISO 15223-1 was EN 15223-1 Removed Standard ISO 11607-2, does not apply to this device Removed footnotes of EN ISO 14971, EN 60601-1-6, EN 62304 and EN 62366-1 Statement text updated	4.0	17 Aug 2017
Model number: updated Programmer Application Software VSF21 with revision 8.0	5.0	25 Sep 2017
Clarification of VSF21 revision 8.0 for both programmers.	6.0	26 Sep 2017
Updated to reflect MDT30130338 rev 1.0 standards changes from ISO 15223-1:2012 to EN ISO 15223-1:2016	7.0	16-Jul-2018
Updated EN 45502-1 title. Added “Implants for surgery”	8.0	10-Jan-2019
Updated document information to align with current template revision A Updated to match Agile MAP revision numbering convention Added Amendment 1:2019 to EN ISO 11135:2014 Changed EN 60601-1:2006+A1:2013 to EN 60601 1:2006+A12:2014. The change is due to the incorporation of technical corrigendum July 2014 (technical correction of Figure 12).	A	18-Dec-2020
Updated EN ISO 14971 revision from 2012 to 2019 Added standards ISO 14708-1 and ISO 14708-2 Updated EN ISO 10993-1 revision from 2009/AC:2010 to 2020 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019	B	Upon Approval

vitatron

EC Declaration of Conformity

Manufacturer:	Vitatron Holding BV Endepolsdomein 5 6229 GW Maastricht The Netherlands
EC Representative:	N/A
Description of device concerned:	*G-Series Implantable Pulse Generator; Programmer Application Software*
Model number:	*G20A2, G70A2, VSF21*
Variants:	*VSF21 v8.0 (Programmer 2090 and 29901)*
GMDN Code	47265 Dual-chamber pacemaker, rate-responsive 47267 Single-chamber pacemaker, rate-responsive 47206 Cardiac Pulse Generator Software
Classification, rule	AIMD
Conformity Assessment procedure:	*Annex 2.3 with Annex 2.4*
EC Certificate number:	*Implantable Pulse Generator: 2008481DE24* *Programmer application software: 2008481DE20*
EC Quality System Certificate:	*2008481CE01*
Name of Notified Body:	*DEKRA Certification B.V.* *Meander 1051* *6825 MJ Arnhem* *The Netherlands*
Identification Number Notified Body:	*0344*
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Vitatron, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC [1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to change record***

Place: Maastricht

Date: ***Refer to document approval date in the change record***

Name: Cor Mathijsen

Title: EC Management Representative

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] Including amendments issued in the years following

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements following the applicable EC Directive.

The below mentioned Standard(s) apply to all the product(s) mentioned under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be labeled "STERILE"- Part 1: Requirements for terminally sterilized medical devices
EN 1041	2008 + A1:2013	Information Supplied by the Manufacturer with Medical Devices
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 45502-1	2015	Implants for surgery - Active Implantable Medical Devices - Part 1. General requirements for safety, marking and information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active Implantable Medical Devices - Part 1. General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery - Active Implantable Medical Devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN ISO 10993-1	2020	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing within a Risk Management Process
ISO 10993-7	2008 + Amd1:2019	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
EN ISO 11135	2014 + A1:2019	Sterilization of medical devices – Validation and routine control of Ethylene Oxide sterilization
EN ISO 14971	2019	Medical devices-Application of risk management to medical devices
EN ISO 11607-1	2009 + A1:2014	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 5841-3	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
EN 62366-1	2015	Medical devices – Application of usability engineering to medical devices
EN 60601-1-6	2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
EN 60601-1[2]	2006 + A12:2014	Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance
EN 62304	2006 + A1:2015	Medical device software – Software Life-cycle processes

[2] Full Compliance (only clause 14 is applicable)

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE28

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

For the product / product category

Leads for Brady IPGs and their auxiliary components

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 30 April 2018

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 29 September 2023
Issued for the first time: 30 April 2018
Reissued: 29 September 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE28

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Medtronic Inc.

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

This certificate covers the following product(s):

CapSure Sense MRI™ SureScan® models 4074, 4574
CapSureFix Novus MRI™ SureScan ® model 5076
CapSure Z Novus MRI SureScan TM models 5054, 5554

Initial date: 30 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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