ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

## No. G12 039709 1406 Rev. 02

**Manufacturer:**

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

SRN Manufacturer - US-MF-000019977

**Authorized Representative:**

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G12 039709 1406 Rev. 02

**Report No.:** 72193584

**Preceding Certificate No.:** G12 039709 1406 Rev. 01

**Valid from:** 2024-02-12
**Valid until:** 2027-03-27

**Date of Initial Issuance:** 2022-03-28

[redacted]
Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2024-02-12


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
BS-MDR-099

TÜV SÜD Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

## No. G12 039709 1406 Rev. 02

| | |
|---|---|
| **Classification:** | Class III |
| **Device Group:** | C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED |
| **Intended Purpose:** | - |
| **Classification:** | Class III |
| **Device Group:** | C02010499 - ARRHYTHMOLOGY MULTIPOLAR LEADS - OTHER |
| **Intended Purpose:** | - |
| **Classification:** | Class III |
| **Device Group:** | C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS |
| **Intended Purpose:** | - |
| **Classification:** | Class III |
| **Device Group:** | C020303 - ARRHYTHMOGENIC FOCI ABLATION LEADS VIA OTHER ENERGY SOURCES |
| **Intended Purpose:** | - |
| **Classification:** | Class III |
| **Device Group:** | C020301 - ARRHYTHMOGENIC FOCI RADIOFREQUENCY ABLATION LEADS |
| **Intended Purpose:** | - |
| **Classification:** | Class III |
| **Device Group:** | C020599 - CARDIAC DIAGNOSTIC DEVICES - OTHER |
| **Intended Purpose:** | - |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | - |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2022-03-28 | 72172299 | - |
| 01 | 2023-11-15 | 72194519 | Supplemented: Device(s)/group of device(s) added |
| 02 | 2024-02-12 | 72193584 | Supplemented: Device(s)/group of device(s) added |



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

# EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

## No. G70 039709 1384 Rev. 00

**Manufacturer:**

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

**SRN Manufacturer:** US-MF-000019977

**Authorized Representative:**

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1384 Rev. 00

**Report No.:** 713203021

**Valid from:** 2022-02-23
**Valid until:** 2027-02-22

[redacted]

**Issue date:** 2022-02-23

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

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

# EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

## No. G70 039709 1384 Rev. 00

| | |
|---|---|
| **Classification:** | III |
| **Device Group:** | C02010499 - ARRHYTHMOLOGY MULTIPOLAR LEADS - OTHER |
| **Basic UDI-DI:** | 0763000B000040072 |
| **Intended Purpose:** | To collect intracardiac electrograms from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies.<br>The mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front family of cardiac cryoablation catheters. |
| **Device(s):** | Achieve<br>Article/Model Numbers<br>- 990063-015<br>- 990063-020<br><br>Achieve Advance<br>Article/Model Numbers<br>- 2ACH15<br>- 2ACH20<br>- 2ACH25 |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | ./. |

-



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®

# EU MDR Declaration of Conformity (DoC)

| | |
|---|---|
| **Manufacturer:** | Medtronic, Inc.<br>710 Medtronic Parkway<br>Minneapolis MN 55432 USA |
| **Manufacturer SRN:** | US-MF-000019977 |
| **Authorized Representative:** | Medtronic B.V.<br>Earl Bakkenstraat 10<br>6422 PJ Heerlen<br>The Netherlands |
| **Authorized Representative SRN:** | NL-AR-000006050 |
| **Notified Body:** | TÜV SÜD Product Service GmbH<br>Ridlerstraße 65<br>80339 Munich, Germany<br>Notified Body number: 0123 |
| **Conformity Assessment Certificate(s):** | Design Examination Certification: G70 0397091384<br>Quality Management Certification: G12 039709 1406 |
| **Conformity Assessment Procedure:** | Annex IX chapter II |
| **Risk Class:** | Class III |
| **Classification Rule:** | Rule 7 |
| **Intended Purpose:** | The *intended purpose* of the Achieve/Achieve Advance mapping catheter is to collect intracardiac electrograms from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies.<br>The mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front family of cardiac cryoablation catheters. |

**Statement:**

We, Medtronic, Inc., hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

| Union Legislation | Applicable Declaration of Conformity Document Number |
|---|---|
| RoHS 3 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment | D00275956 |

| | |
|---|---|
| **Place:** | Minneapolis, MN |
| **Name:** | Refer to electronic signature |
| **Title:** | Refer to electronic signature |
| **Signature:** | ***Refer to electronic signature*** |
| **Date:** | ***Refer to electronic signature*** |

# Products Covered

| Product Name | Medtronic Product Identifier CFN | Basic UDI-DI |
|---|---|---|
| Achieve™ | 990063-015, 990063-020 | 0763000B000040072 |
| Achieve Advance™ | 2ACH15, 2ACH20, 2ACH25 | |

# Common Specification(s)

Not Applicable

# Revision History

| Revision | Date Effective | Description of Change |
|---|---|---|
| A | TBD | Initial release of document |

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 039709 1144 Rev. 02**

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

**Product Category(ies):** **External pacemakers, diagnostic and ablation catheter, transseptal needles**

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.:** 713159141

**Valid from:** 2020-03-03
**Valid until:** 2024-05-26

**Date,** 2020-02-28

[redacted]
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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# EC Certificate

## EC Design-Examination Certificate

**Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)**
**(Devices in Class III)**

## No. G7 17 08 39709 01118

**Manufacturer:**

**Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

**EC-Representative:**

**Medtronic B.V.**
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

**Product:**

**Catheters for single use**
**Cardiac Balloon Catheters**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

**Report no.:** 713097898

**Valid from:** 2018-02-03
**Valid until:** 2023-02-02

**Date,** 2017-12-06

[redacted]


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





TÜV®

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# EC Certificate
# EC Design-Examination Certificate

**Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)**
**(Devices in Class III)**

## No. G7 17 08 39709 01118

**Model(s):** **Attain Venogram Balloon Catheter 6215**

**Parameters:** ./.

**Facility(ies):** Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA





TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

| Medtronic | Document Title: DoC-6215 | Document Number: BL0003803 |
|---|---|---|
| **EC DECLARATION OF CONFORMITY** | Model 6215 Attain Venogram Balloon Catheter | |

| Revision/History description | Revision level | Impl. Date |
|---|---|---|
| Attain Venogram Balloon Catheter, Model 6215 | - | 29-AUG-2001 |
| Update to implement new EC Rep Address, editorial changes, new CE mark certificate | A | 25-MAR-2004 |
| Update to align CE mark following update of CE mark from OEM, editorial changes | 4.0 | 13-FEB-2008 |
| Updated to support MD Directive 93/42/EEC: Amendment 2007 and New Template. Corrected Issue Date. | 5.0 | 27-APR-2010 |
| Updated Standards, New DoC Template Rev 7.0 | 6.0 | 19-JUN-2012 |
| Updated to add new design certificate number due to CE Renewal; update to latest revision of DoC template 8.0 | 7.0 | 23-JAN-2013 |
| Updated to add new quality system certificate<br>G1 13 02 39709 857 which replaces G1 12 02 39709 781 | 8.0 | 26 June 2013 |
| Added EN ISO 14971:2012 | 9.0 | 25 July 2013 |
| Updated to add new Quality System Certificate number | 10.0 | 27 Mar 2015 |
| Updated approver to Stacey Pivovar<br>Updated referenced Standards for EN ISO 11135, EN ISO 10555, EN ISO 11607,<br>Added EN 62366:2008 to referenced standards<br>Updated titles for EN ISO 11135, EN ISO 10555<br>Updated Compliance for EN ISO 10993-1: 2009/AC:2010 and EN ISO 14971: 2012 | 11.0 | 17 Oct 2016 |
| Update revision of standards EN ISO 11135, EN ISO 10555<br>Updated approver to Kiran Kuppuswamy | 12.0 | 06-Apr-2017 |
| Updated to latest revision of DoC template.<br>Updated to reflect new EC certificate number. New certificate (G7 17 08 39709 01118) replaces certificate (G7 13 01 39709 856) and becomes effective February 3, 2018. As such, validity date updated to reflect February 3, 2018. | 13.0 | 11-Dec-2017 |
| Corrected Directive listing to 93/42/EEC. | 14.0 | 22-Feb-2018 |
| Updated referenced Standards for ISO 11135:2014, and EN 62366-1:2015 | 15.0 | 08-Mar-2018 |
| Updated footnote ([4] Full compliance only for the design changes made to released product) removed to reflect Full Compliance to standard EN 62366-1:2015. | 16.0 | 15-Mar-2018 |
| Updated to reflect new EC Quality System certificate number. New certificate (G1 18 02 39709 01144) replaces certificate (G1 15 02 39709 975). | 17.0 | 26-Apr-2018 |
| Updated to reflect BL0016436 Rev 15.0 standards changes:<br>• From EN 980:2008 to EN ISO 15223 -1:2016<br>• From EN 1041:2008 to EN 1041:2008/A1:2013 | 18.0 | 15-Jan-2019 |
| Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018<br>Updated EC Quality System Certificate number | 19.0 | 21-Oct-2019 |
| Updated to match Agile MAP revision numbering convention<br>Added referral to change record for signatures and approval date<br>Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020<br>Added Amendment 1:2018 to EN ISO 11135:2014 | AA | 01-Apr-2020 |
| Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019 | AB | 12-Oct-2020 |
| Updated EN ISO 14971 revision from 2012 to 2019<br>Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019<br>Added standards ISO 14708-1 and ISO 14708-2 | AC | 10-Sep-2021 |

| | | |
|---|---|---|
| Updated ISO 10993-1:2018 to EN ISO 10993-1:2020 | | |
| This revision is to update the AIMDD Declaration of Conformity to include requirements of amended Regulation (EU) 2023/607<br>Updated to current revision of document template.<br>Updated implementation date of last revision.<br>Updated approver name and title. | AD | Upon Approval |

Medtronic

# EC Declaration of Conformity

| | |
|---|---|
| Manufacturer: | Medtronic Inc.<br>710 Medtronic Parkway<br>Minneapolis MN 55432 USA |
| EC Representative: | Medtronic B.V.<br>Earl Bakkenstraat 10<br>6422 PJ Heerlen<br>The Netherlands |
| Description of device concerned :<br>Model number:<br>Variants: | Attain Venogram Balloon Catheter<br>6215<br>Not applicable |
| GMDN Code and Description | 10688, Angiographic catheter, single-use |
| Classification, rule | Class III, Rule 6 |
| Conformity Assessment Route: | Annex 2.3 with Annex 2.4 |
| EC Certificate number: | G7 17 08 39709 01118 |
| EC Quality System Certificate: | G1 039709 1144 |
| Name & Address of Notified Body: | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 Munich<br>Germany |
| Identification Number Notified Body: | 0123 |
| Conformity with the following standard(s) or other normative document(s) | See Attachment 1 |

Statement:
We, Medtronic, 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 93/42/EEC[1] which apply to them. In addition, Medtronic declares compliance to Article 120 of the Regulation (EU) 2017/745 and the Regulation (EU) 2023/607, amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards to the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607. This declaration applies to all devices specified above distributed from the signature date through the amended Regulation extension date of 31 December 2027. The validity of the certificates listed on this DoC are valid through 31 December 2027.

Validity DoC from date: ***Refer to document approval date in the change record***

Place: Minneapolis

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

Name: Luke Ranta
Title: Engineering Manager

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

**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 of the applicable EC Directive.

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

| Number | Date of issue | Title |
|---|---|---|
| EN 1041 | 2008 + A1:2013 | Information supplied by the manufacturer with medical devices |
| EN ISO 10555-1 | 2013 Cor 2014 | Sterile, Single-Use Intravascular Catheters - Part 1: General Requirements |
| 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 |
| ISO 11135 | 2014 +A1:2019 | Sterilization of health-care products - Ethylene Oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices |
| EN ISO 11607-1 | 2020 | Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems |
| EN ISO 14971 | 2019 | Medical devices – Application of risk management to medical devices |
| EN ISO 15223-1 | 2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03) |
| EN 62366-1 | 2015 | Medical devices – Part 1: Application of usability engineering to medical devices |
| 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 |
| ISO 14708-2 | 2019 | Implants for surgery - Active implantable medical devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) – Second edition |

CERACARTA® SpA

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipments.
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking systems, lottery.
Rfid labels and chain solutions.

Sede: Via Secondo Casadei, 14 - 47100 Forlì ITALY
Tel. 0039-0543-780055 • Fax 0039-0543-781404
Website: www.ceracarta.it • E-mail: info@ceracarta.it
Capitale Sociale € 1.000.000 int. vers.
P.I. / C.F. 00136740404 / VAT. N. IT 00136740404
Reg. Imprese Forlì-Cesena n. 3422 REA n. 72646 / n. FO 006883

Cassa dei Risparmi di Forlì • Rolo Banca 1473 • BNL
Banca Intesa BCI • Cassa di Risparmio di Bologna •
Ist. Banc. S. Paolo di Torino • Banca di Roma

# DECLARATION OF CONFORMITY

of the device named "GELS & CREAMS", "ECG, EEG & TENSE ELECTRODES" , "MOUTHPIE "PLATES FOR ELECTROSURGICAL", "SPECULUM" and "OTHER ACCESSORIES " produced company Ceracarta on the basis of the essential requirements, see enclosure I of the di *93/42/CEE,* as prescribed in enclosure VII of the above directive.

The writing company Ceracarta located in Via secondo Casadei , 14 Forlì, manufacturer of the product named , " GELS & CREAMS", "ECG, EEG & TENSE ELECTRODES" , "MOUTHPIECES", "PLATES FOR ELECTROSURGICAL", "SPECULUM" and "OTHER ACCESSORIES " , ***declares under its own responsability*** *that such a device satisfies all the requirements of directive 93/42/CEE about medical devices and in particular that:*

- the Device in object satisfies the essential requirements as per in Enclosure I of Directive 93/42/CEE;
- the Device in object must be considered as belonging to **Class I**;
- the Device in object must be esclusively used together with electro-medical instruments for recording, diagnosis and therapy, which base their functioning upon the measuring of energy flows of electric, magnetic and ultrasound type;
- The manufacturer has prepared and keeps the technical files updated in accordance with enclosure VII, section 3 of the directive itself.
- Such documentation is available at the headquarters of Ceracarta, for any reference by the entitled bodies.

[redacted]er

(Logotipas) Ceracarta S.p.A.

Atitikimo Europos Sąjungos taisyklėms deklaracija

Kompanija Ceracarta, esanti adresu Via secindo Casadei 14, Forli, Italija, gaminanti šiuos produktus: „Geliai ir kremai“, „EKG. EEG ir TENS elektrodai“, „Kandikliai“, „Neutralūs elektrochirurginiai elektrodai“, „Spekulės“ it „Kiti priedai“ atsakingai patvirtina , kad šie gaminiai gaminami pagal Europos Sąjungos Medicinos Prietaisų Direktyvos 93/42/EEC reikalavimus

(Spaudas)
(Parašas)

Vertimas tikras:

Rolanas Širmonaitis
2007 m. gruodžio 3 d.

CERACARTA S.p.A.

ISO 9001:2015 EN ISO 13485:2016

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipments.
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking system, lottery.
Rfid labels and chain solutions.

Sede (Head office and works) :
Via Secondo Casadei, 14 - 47122 FORLI' – ITALY
Tel : 0039 0543 780055 • Fax : 0039 0543 781404
http : // www.ceracarta.it • e-mail : info@ceracarta.it.
Capitale Sociale : € 1.000.000 int. vers.
Registro Imprese FORLI'-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLI' N. 72646 – N. MECC. FO 006863

FORLì,27 February 2023

**SUBJECT:TRANSITION TO MDR 2017/745.**

We hereby declare that the company Ceracarta S.p.A. is concluding the certification process for the passage of the doctors of its manufacture to the MDR 2017/745 Regulation.

However, we would like to point out that on 16 February 2023, the European Parliament voted in favour of the transitional provisions for medical devices.
The extension to the 2024 dead line of the transitional period for the transitionto Directive 93/42/EEC on medical devices was therefore approved. **This extension will make our CE certificates valid again according to Directive 93/42/EEC until 31/12/2028**.
In fact, our medical devices comply with all the conditions set out in letter a) of Article 1 of the European Commission's proposal on the amendment of transitional provisions (*Proposal for a* Regulation of the *European Parliament and of the Council amending Regulation EU 2017/745 as regards the transitional provisions for certain* medical devices *and in vitro diagnostic medical devices).*

**In conclusion, our medical devices, in addition to being about to conclude the transition process to MDR 2017/745 with the obtaining of a certificate in accordance with this Regulation, will be able to take advantage of the postponement of the transitional period that will make valid the placing on the market of devices compliant with Directive 93/42 / EEC until 31/12/2028.**

In faith
Dr. Alessandro Bandini
Chairman of Ceracarta S.p.A.

CERACARTA SPA
Bandini Alessandro

[redacted]

CERACARTA S.p.A.

ISO 9001:2015 EN ISO 13485:2016

Visos elektrodiagnostinės įrangos diagramos.
Eksploatacinės medžiagos ir elektromedicininiai priedai.
Pramoninės įrašymo įrangos kortelės.
Specialūs ritinėliai ir siuntiniai mokesčių surinkimo, kontrolės ir loterijų sistemoms.
Radijo dažnių etiketės ir integruoti sprendimai.

Visų elektrodiagnostikos įrangos diagramų dokumentai.
Vienkartiniai ir elektromedicininiai priedai.
Chart Papers pramoniniai įrašymo prietaisai.
Specialūs ritinėliai ir fanfolds bilietų tikrinimo sistemai, loterijai.
Rfid etikečių ir grandinių sprendimai.

Pagrindinė buveinė ir darbai : Via
Secondo Casadei, 14 - 47122 FORLI' – ITALIJA Tel.: 0039
0543 780055 • Faksas: 0039 0543 781404 http : //
www.ceracarta.it • el. paštas: info @ ceracarta .
Akcinis kapitalas: 1 000 000 € tarpt. link.
Įmonės registras FORLI'-CESENA PI /
CF / VAT.N. IT 00136740404 REA FORLI'
N. 72646 – N. MECC. FO 006863

FORLì, 2023 m. vasario 27 d

TEMA: PERĖJIMAS PRIE MDR 2017/745.

Pareiškiame, kad įmonė Ceracarta SpA baigia sertifikavimo procesą, kad jos gamybos gydytojai atitiktų MDR 2017/745 reglamentą.

Tačiau norime atkreipti dėmesį, kad 2023 m. vasario 16 d. Europos Parlamentas balsavo už pereinamojo laikotarpio nuostatas dėl medicinos prietaisų.
Todėl buvo patvirtintas pereinamojo laikotarpio perėjimo prie Direktyvos 93/42/EEB dėl medicinos prietaisų termino pratęsimas iki 2024 m. Dėl šio pratęsimo mūsų CE sertifikatai vėl galios pagal Direktyvą 93/42/EEB iki 2028-12-31.

Iš tikrųjų mūsų medicinos prietaisai atitinka visas sąlygas, išdėstytas Europos Komisijos pasiūlymo dėl pereinamojo laikotarpio nuostatų pakeitimo ( Europos Parlamento ir Tarybos reglamento, iš dalies keičiančio Reglamentą ES 2017/745) 1 straipsnio a punkte. dėl pereinamojo laikotarpio nuostatų, taikomų tam tikriems medicinos prietaisams ir in vitro diagnostikos medicinos prietaisams).

Apibendrinant galima pasakyti, kad mūsų medicinos prietaisai ne tik tuoj baigs perėjimo prie MDR 2017/745 procesą, kai bus gautas sertifikatas pagal šį reglamentą, bet ir galės pasinaudoti pereinamojo laikotarpio atidėjimo galimybėmis. iki 2028-12-31 galioja prietaisų, atitinkančių direktyvą 93/42/EEB, pateikimas į rinką.

Tikėjime
Dr. Alessandro Bandini
Ceracarta SpA pirmininkas

CERACARTA SPA
Bandini Alessandro

[redacted]