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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 006868

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.

Dr. F.A.Fusconi
Marketing & Sales Manager
Ceracarta Spa

CERACARTA s.p.a.

(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.

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

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 16 02 77608 012

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

EC-Representative:

Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
IRELAND

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

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.: 713078138

Valid from: 2016-04-17
Valid until: 2021-04-16

Date, 2016-04-05

Stefan Preiß

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

TÜV®

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

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 16 02 77608 012

Facility(ies):

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731, USA

Covidien (Davis & Geck Caribe, Ltd.)
Zona Franca de San Isidro, Carretera San Isidro Km 17, Santo Domingo, DOMINICAN REPUBLIC

Covidien
Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C., MEXICO

Covidien Deutschland Manufacturing GmbH
Gewerbepark 1, 93333 Neustadt/ Donau, GERMANY

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

Covidien Medical Products (Shanghai) Manufacturing L.L.C.
Building#10,789 Puxing Road, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA

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

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EC SERTIFIKATAS

Pilna kokybės užtikrinimo sistema

Direktyva 93/42/EEC Medicininiams prietaisams (MDD), Annex II išskyrus (4)
(IIa, IIb arba III klasės prietaisams)

Nr. G1 16 02 77608 012

Gamintojas : **Covidien IIc**
15 Hampshire Street
Mansfield, MA 02048
JAV

EC atstovas: **Covidien Ireland Limited**
IDA Bussiness ir Technology Park
Tullamore
Airija

Produktų
Kategorijos: Medicininiai instrumentai, chirurginiai produktai ir hemostatinės medžiagos:
Chirurginiai siūlai, lopeliai ir pleistrai;
Endoskopiniai instrumentai ir priedai jiems, įskaitant ir lubrikantus;
Chirurginiai siuvimo aparatai, kabučių aplikatoriai ir priedai;
Pagrindiniai chirurginiai instrumentai;
Implantuojamos žaizdų perrišimo medžiagos;
Ultragarsiniai chirurginiai prietaisai ir priedai;
Siurbimo/plovimo prietaisai ir priedai;
Artroskopiniai inplantai, instrumentai ir priedai;
Kaulinis vaškas;
Laikini širdies stimuliacijos laidai.

Sertifikuojantis asmuo TUV SUD Product Service GmbH deklaruoja, kad aukščiau paminėtas gamintojas atitinka kokybės užtikrinimo sistemą dizaino, gamybos ir galutinio inspektavimo srityje atitinkamiems prietaisams/prietaisų kategorijoms pagal MDD Annex II.
Ši kokybės užtikrinimo sistema atitinka šios direktyvos reikalavimus ir yra periodinės patikros subjektas.
III klasės prietaisams papildomas Annex II (4) yra privalomas.

Pranešimo nr. 713078138

Galioja nuo: 2016-04-17
Galioja iki: 2021-04-16

Data, 2016-04-05 Stefan Preis

TUV SUD Product Service GmbH yra sertifikuojantis asmuo su identifikaciniu Nr. 0123