www.imq.it

CISQ is a member of

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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 9190.CRC3

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

Digitally signed by
Date: 2022.11.22 15
Reason: MoldSign S
Location: Moldova

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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FEDERAZIONE CISQ

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ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

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IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale.
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years.

IMQ

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FEDERAZIONE CISQ
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CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)
VIA GRAMADORA 12/14 - 47122 FORLI' (FC)
has implemented and maintains a

Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2020 - 09 - 29**
Expires on: ***2023 - 10 - 07***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 112265

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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CERTIFICATO N.
CERTIFICATE N. 9124.CRC4

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

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	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ

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FEDERAZIONE CISQ

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ALLEGATO N. **9124.CRC4-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
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IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

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L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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ALLEGATO N. **9124.CRC4-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

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CERACARTA S.p.A.

ISO 9001:2008 EN ISO 13485:2012

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

Messrs

Medicines and Medical Devices Agency

Forlì, 3rd August 2022

We, CERACARTA SPA V having a registered office at Via Secondo Casadei 14,47122 Forlì(FC)-Italy, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as **Authorized representative** in correspondence with the conditions of LAW No. 102 from 09.06.2017 regarding medical devices.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

Manufacturer: **Ceracarta S.p.A.**

Address: **Via Secondo Casadei, 14 47122 Forlì - ITALY**

DECLARES

that

THE RECORDING "THERMAL" AND/OR "INK" PAPERS IN THE MEDICAL FIELD for "ECG", "EEG","CTG" and papers for laboratory tests (including the model M 1911 A),

identified and classified in the

Technical file ,comply with the directive about medical devices (DIRECTIVE 93/42/CEE as amended by 2007/47/EC).

In addition to this, we precise that:

- according to the Directive 93/42/EEC the listed products are medical devices belonging to class I with function of measure.
- they are subject to the regulations of the Attachment I of the above mentioned directive;
- the evaluation of the device was in accordance with Annex V of that Directive, by the certified body IMQ S.p.A. – CE0051;
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2008

EN ISO 13485:2012

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **"ECG GEL / ECO SUPERGEL ."** ***(BASIC UDI-DI 8059170GC004NN)***,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies;
- the Dispositive 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;
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro
CERACARTA s.p.a.

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015

EN ISO 13485:2016

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **TOP TRACE ECG ELECTRODES *(BASIC UDI-DI 8059170EL001PR)***,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.

In addition:

- the device is tested according to the voluntary Association for the Advancement of Medical Instrumentation (AAMI) standard requirements for electrical performance for disposable ECG electrodes (ANSI/AAMI EC 12:2000) and test results meet or exceed these performance standards.
- the device is tested and it is found to be acceptable for use,according to:

UNI EN ISO 10993-1:"Biological evaluation of medical devices" ;

UNI EN ISO 10993-5 :"Biological evaluation of medical devices :tests for in vitro cytotoxicity";

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ISO 9001:2015 EN ISO 13485:2016

CERACARTA® S.p.A.

UNI EN ISO 10993-10 :"Biological evaluation of medical devices :tests for irritation and sensitization".

• Ceracarta does not use any latex/PVC materials or ingredients in the manufacturing of our electrodes;

• Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.
Alessandro Bandini

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ISO 9001:2015

EN ISO 13485:2016

CERACARTA S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **"COMPATIBLE PAPER FOR SONY UPP 110 S / HG / HD ROLLS", (BASIC UDI-DI 8059170CA001LN)**,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro
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ISO 9001:2015 EN ISO 13485:2016

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPC-21L
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Color Printing Pack
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02261

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110S
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02266

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110HG
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02267

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110HD
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-10

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02280

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

ECO SUPERGEL FOR ULTRASOUNDS

Available in "CLEAR" version too.

ECO SUPERGEL FOR ULTRASOUNDS
The carefully designed composition of this gel means that it is particularly suitable for diagnostic exams and ultrasound treatments.

- No salt is contained to prevent damaging the probes
- It does not cause skin irritation even after many scans
- Excellent viscosity (80,000 RPM5-STD 18°)
- Rapid transmission speed (1.48)
- Perfect acoustic impedance
- Extremely efficient
- Bacteriostatic levels lower than admissible even by the most stringent international standards

AVAILABLE IN FOUR VERSIONS:

- 260 g (sub-carton 12 bottles - master carton with 96 pieces)
- 600 g (box with 5 bottles - carton with 30 pieces)
- 1 kg (box with 4 bottles - cartons with 24 pieces)
- 5 kg (individual pack with bottle/refill - box with 4 pieces)

NEW !
600 gr. Bottle now available

A smart and handy bottle, easy to be used, perfectly combining both economic and practical qualities.

ECG SUPERGEL & SUPERCREAM

ECG SUPERGEL & SUPERCREAM

In order to have high-quality ECG recordings for a long time it is essential to have a really "super" gel. The composition studied for the gel or for the cream (same characteristics, but with a lightly perfumed cosmetic base) actually allows for an improvement of the signal, preventing any kind of anomaly and providing users with a constantly reliable monitoring.

- No salt contained
- It does not damage the electrodes it comes into contact with
- Soluble in water
- It does not irritate even the most delicate skin types
- Not greasy
- Optimal viscosity
- Bacteriostatic levels lower than admissible even by the most stringent international standards
- PP-HDPE 260 g container with total guarantee (box with 12 bottles - master carton with 96 pieces)

SUPER CLEAN

SUPER CLEAN

Degreasing paste apt for skin cleansing before EEG-EP-ECG recording;
Allowing to reduce impedence down to minimum levels when a signal devoid of any adulteration is needed.

. Water-based, viscous gel
. Free from colouring agents, non irritating
. 160 g. PLTHD-PLTLD bottle (24 pcs per box)

EEG/EMG SUPERCREAM & PASTE

EEG SUPERCREAM

Water-soluble and highly conductive cream for EEG-EP-EMG recording

. Non irritating, non greasy
. Non damaging probes
. 260 g. PP-HDPE bottle (12 pcs per box – 8 boxes per carton)

EEG "SUPERIOR QUALITY" PASTE

Highly adhesive & above-average conductive paste, suitable for disk electrodes

. Pale white colour
. Water-soluble
. PH from 6.6 to 7
. Low impedance
. 250 g. jar (18 boxes per carton)

AQUASONIC
PARKER

AQUASONIC – PARKER

Ceracarta is the official distributor of this gel for ultrasounds famous all over the world.
The quality and characteristics of this gel are undoubtedly excellent.
Available in three versions:

- 250 g (pack with 12 bottles - boxes with 72 pieces)
- 5 kg (individual package with bottle/refill - box with 4 pieces)
- 20 g Sterile gel in a small metal bag wrapped inside another sealed bag - (48 pieces per box)

CUSTOMISED GEL

CUSTOMISED GEL

Ceracarta can provide solutions for important customers who, for any reason, might require a customised gel packaging.
At no extra cost you can have bottles or containers graphically designed to meet each customer's taste and requirements.

CE
Products EC compliants

ceracarta

COMPANY
WITH QUALITY SYSTEM
CERTIFIED BY DNV
ISO 9000

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