

**CERTIFICATO N.
CERTIFICATE N. 9190.CRC3**

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

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLÌ (FC) Italy

UNITÀ 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 ATTIVITÀ / 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 electrodes for ECG. Production management and placing on the market of electrodes 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 26-11-2002	EMISSIONE CORRENTE CURRENT ISSUE 04-10-2023	SCADENZA EXPIRY 07-10-2026
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IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



MS N° 0005MS

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



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale. CISQ
is the Italian Federation of management system
Certification Bodies.

ALLEGATO N. 9190.CRC3-1
ANNEX N.

CERACARTA SPA

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

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.

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 electrodes for ECG. Production management and placing on the market of electrodes 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

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
	26-11-2002	04-10-2023	07-10-2026



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



MS N° 0005MS

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



www.cisq.com

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ALLEGATO N. 9190.CRC3-2
ANNEX N.

CERACARTA SPA

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

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
	26-11-2002	04-10-2023	07-10-2026



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

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

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) Italy

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

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 electrodes for ECG. Production management and placing on the market of electrodes 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

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **2023/10/04**

Expires on: **2026/10/07**

Registration Number: **IT – 112265-9190.CRC3**



Alex Stoichitoiu
President of IQNET



Mario Romersi
President of CISQ



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

IQNET Members*:

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 **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea
LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

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

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) :
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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 FORLÌ-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLÌ N. 72646 - N. MECC. FO 006863

FORLÌ, 20th March 2023

SUBJECT: EXTENSION BY THE EUROPEAN PARLIAMENT OF THE VALIDITY OF CE CERTIFICATES ACCORDING TO DIRECTIVE 93/42 / EEC AS PER EU REGULATION 2023/607 OF 15 MARCH 2023

We hereby communicate the following:

- 1) On 16th February 2023, the European Parliament voted in favour of the transitional provisions for medical devices.

The extension to the 2024 deadline of the transitional period for the transition to Directive 93/42/EEC on medical devices was therefore approved. **Such extension will make our CE certificates valid again according to Directive 93/42/EEC until 31/12/2028.**

- 2) On 15th March 2023, the European Parliament published in the Official Journal of the European Union the extension of the validity of certificates issued by Notified Bodies in accordance with Directive 93/42/EEC.

So from that date, the proposal of 16th February 2023 becomes law and **CE certificates remain valid even after the deadline if they comply with the provisions of Article 1 of EU [Regulation 2023/607](#) that we attach to this.**

In conclusion, the following is stated:
our medical devices:

-MEDICAL RECORDING CHART PAPERS

Certificate CE 0051 number 1976/MDD (class Im)

-STERILE ULTRASOUND TRANSMISSION GEL AND STERILE LUBRICATING GEL

Certified CE0051 number 1974/MDD (class IIa)

-ACCESSORIES FOR ELECTROSURGICAL UNIT

Certified CE0051 number 1974/MDD (class IIb)

comply with the conditions set out in letter a) of Article 1 of both the European Commission's proposal (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) and the subsequent EU Regulation 2023/607.

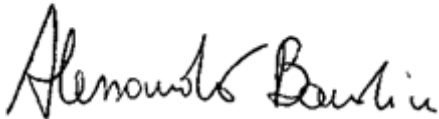
For this reason, the relevant **[CE certificates according to MDD 93/42/EEC ARE VALID EVEN AFTER THE EXPIRY DATE and until 31/12/2028, thus making the placing on the market of these devices valid until that date.](#)**



However, we point out that the process of transition to MDR 2017/745 for our devices is already underway, assuming that certificates will be obtained in accordance with this Regulation in a short time.

Sincerely,

Dr. Alessandro Bandini
Chairman of Ceracarta S.p.A.
CERACARTA SPA
Bandini Alessandro



Since 1960 at your service – Since 1960 at Your Service