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CERTIFICATO N. 0967.2019
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE AMBIENTALE DI
WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

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

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)
E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 14001:2015

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 tramite processo di stampaggio. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radiofrequenza (RFID) tramite processo di stampaggio. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi tramite processo di miscelazione dei vari prodotti chimici ed imbottigliamento. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG tramite processi di accoppiamenti delle materie prime e taglio a misura. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti
Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT-09

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	EMISSIONE CORRENTE	SCADENZA
	<i>FIRST CERTIFICATION</i>	<i>CURRENT ISSUE</i>	<i>EXPIRY</i>
	2019-06-05	2019-06-05	2022-06-04

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



www.cisq.com



SGA N° 006 D

IAF: 07, 09, 19, 12, 29

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento
Processes related to underlined IAF sectors are not yet covered by accreditation

Organismo di Certificazione Federato CISQ
www.imq.it

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

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

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



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.



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)

*has implemented and maintains a
Environmental 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 by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrodes for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

which fulfills the requirements of the following standard:

ISO 14001:2015

Issued on: **2019 - 06 - 05**

Expires on: **2022 - 06 - 04**

*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 - 125879



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
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 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
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

CERTIFICATO CE

Certificato n. 1976/MDD

Dichiarazione di approvazione del sistema qualità

(Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CERACARTA SPA

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

mantiene negli stabilimenti di:

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

un sistema qualità che assicura la conformità dei seguenti prodotti:

Carte per registrazione ad uso medico

Modd. come da documento allegato "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valido solo se provvisto di timbro IMQ.
Marca Ceracarta

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'Allegato V.

Riferimento pratiche IMQ:

DM17-0017248-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.

Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

IMQ



IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

EC CERTIFICATE

Certificate No 1976/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

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

manages in the factories of:

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

a quality assurance system ensuring the conformity of the following products:

Electromedical recording chart paper

Type ref. as to annexed document "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valid only if provided with IMQ stamp.
Trade mark Ceracarta

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:
DM17-0017248-01.

**This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.**

Date: 2017-11-18

Expiry Date: 2022-11-17

IMQ



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This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

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 equipment.
 Disposable and electromedical accessories.
 Chart Papers industrial recording instruments.
 Special rolls and fanfolds for tickets checking systems.
 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

ELENCO CARTE DIAGRAMMATE CLASSE I F.M.

REV.15 - 16/10/2017

Codice famiglia identificativo	Descrizione famiglia
22.01	Pacchi stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
21.01	Rotoli stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
32.01	Schede e dischi stampati medicali





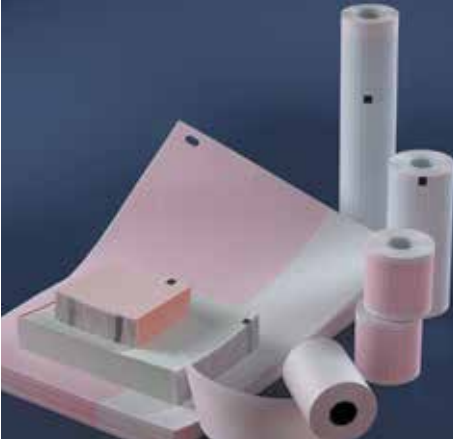
CHART PAPERS



Widest choice of articles for a variety of sectors including:
ELECTROCARDIOGRAMS - ELECTROENCEPHALOGRAMS - FOETAL MONITORING - NEUROLOGY
- GYNAECOLOGY - PNEUMOLOGY - INTENSIVE CARE UNITS - POLIGRAPHS - RESUSCITATION
- ULTRASOUND SCANS - LABORATORY ANALYSIS

If requesting an offer, please state: model and instrument code, where possible the paper code and, in any case, the size. For EEG z-folds colour and line distance.

PAPERS FOR ECG



FROM THE SIMPLEST SINGLE-CHANNEL INSTRUMENTS TO THE MOST COMPLEX APPLIANCES FOR STRESS TESTS OR FOR PARTICULAR MONITORING OF CORONARY UNITS, THE BEST SOLUTION FOR ALL QUALITY AND OPERATION REQUIREMENTS CAN BE FOUND IN THE ARTICLES PRODUCED BY CERACARTA. RESEARCH AND STUDY OF THE BEST SUPPORT FOR EACH SPECIFIC APPLIANCE DERIVES FROM AN IN-DEPTH KNOWLEDGE OF THE INSTRUMENTS ON WHICH VARIOUS TYPES OF PAPER ARE USED.

Furthermore constant checks, detailed control and regular technological updating ensure continuously high efficiency in recording. For particular requirements we can supply paper which guarantees conservation of the recording trace for more than 20 years. Ceracarta always guarantees the absolute reliability of its paper with respect to all the instruments available commercially, even the less common.



PAPERS FOR CTG



THE EXTREMELY PRECISE PRINTING OF DIAGRAMS AND BASE SCALES AND THE GAUGED SENSITIVITY OF THERMAL PAPER ARE ESSENTIAL FOR THE BEST FUNCTIONING OF THE FOETAL MONITORING EQUIPMENT AND, THEREFORE, AN EXCELLENT DIAGNOSTIC READING.

Ceracarta has paid special attention to these details, manufacturing products which, also due to the perfection of the lateral holes and the numbering of each page, and owing to the accuracy of the regulating sensors, are among the best available commercially, where too often paper of insufficient efficiency is on offer. Ceracarta represents a guarantee, not found everywhere, also in the sector of foetal monitoring.



PAPERS FOR EEG



IN VIEW OF THE PARTICULAR NATURE OF EEG INSTRUMENTS AND THE DIVERSITY OF THEIR FUNCTIONS, PAPER MANUFACTURERS MUST BE EXTREMELY CAREFUL WHEN EVALUATING THE VARIOUS CHARACTERISTICS OF THE APPLIANCE AND BE VERY FLEXIBLE IN VARYING BASIC RAW MATERIALS.

A great priority must be given to the perfect running of the paper and to its excellent receptivity as for the writing pen. Through its paper Ceracarta constantly guarantees best results also in this sector, even during long recordings, thanks to its perfect adaptability, specifically and attentively researched, for all types of instruments.



PAPERS FOR ANALYSIS LABORATORY AND LABELS



THE APPARENT SIMPLICITY OF PAPERS FOR INSTRUMENTS OF ANALYSIS HAS OFTEN INDUCED CONSUMERS TO BE EASILY SATISFIED TO THE DETRIMENT OF THE QUALITY OF THE REPORT AND, ESPECIALLY OF THE CONSERVATION OVER TIME OF THE DOCUMENTATION RELATING TO THE ANALYSIS.

Also in this field, specialisation is crucial and the quality of the raw materials is of a primary importance. Ceracarta is at your disposal with rolls and packs for all types of instruments for laboratories, guaranteeing optimal functioning and a perfect result.



CERACARTA PRODUCES THERMAL PAPER LABELS, PAPERS FOR THERMAL TRANSFER PRINTERS AND POLYESTER FILMS FOR ANALYSIS LABORATORIES AND TRANSFUSION CENTRES, MANUFACTURED WITH SPECIAL MATERIALS AND ADHESIVES, FOR ALL REQUIREMENTS.

Whatever the use (labels for test tubes, medical reports, radiological envelopes or "blood bags"), an excellent outcome is ensured. Ceracarta has implemented a division for the production of labels and tickets with a microchip (RFID technology) to be applied also to the medical field.





THE COMPANY CERACARTA

- We are leaders in Europe for the manufacturing of paper for electrical diagnostic instruments and industrial recording with over 60 years' experience in the medical sector.
- Advanced technologies, equipment and methodical quality controls for the production of specific chart and plain papers for all diagnostic equipments available on the international market.
- Superior quality materials and absolute manufacturing precision for perfect diagnosis.
- Study and research centre to meet any specific need or customisation requirement and client consulting service.
- Documents and samples sent on request.
- ISO 9001: 2015 - ISO 13485: 2016 - ISO 14001: 2015 - ISO 45001: 2018 - EC CERTIFICATION - COUNCIL DIRECTIVE 93/42/ EEC - MDR 2017/745.



THE WAREHOUSE

WAREHOUSE

Perfect service offered to customers in terms of guaranteeing delivery times, the great care paid when choosing the most suitable form of packaging for the type of shipment, as well as the perfect correspondence between the product supplied and what is requested.

- Optimal management of the stock related to production programmes: all this is guaranteed by a computerised system which now supports the traditional bar code, the revolutionary and brand-new radio frequency transponder system (TAG).
- Professional skill and competence of our staff ensure an ideal service for customers.



MACHINES AND EQUIPMENTS

MACHINES AND EQUIPMENTS

After the new premises were set up, the machineries have been almost completely replaced or modified in order to both improve the quality of the product and to accelerate the production process with lower costs for the customer. The whole production system has the advantage of a double check: on the one hand the specialised technical staff and the automated computer control on the other.

