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.

Digitally signed by Ceaicovschi Tudor
Date: 2021.04.14 12:50:42 EEST
Reason: MoldSign Signature
Location: Moldova

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

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

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

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

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

CERACARTA® S.p.A.

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 sys
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

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

2017-11-18

CSQ

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

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.* 0967.2019

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 canto terzi tramite processo di miscelazione dei vari prodotti chimici ed imbottigliamento. Commercializzazione ed immissione in commercia 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 commercia 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 *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2019-06-05	2019-06-05	2022-06-04

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

IMQ

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGA N° 006 D

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

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

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

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
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)

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 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

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.

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

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 510679**

Issued To: **Fiab SpA**
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

In respect of:

The manufacture of sterile and non sterile nasal cannulae, masks, kits and accessories for oxygen and aerosol therapy.
Those aspects of Annex V related to securing and maintaining sterility in the manufacture of femoral compression discs, connection cables, touch-proof plug adaptors, heart wire insulators, electrosurgical pencil holster and cleaning pad for electrosurgical pencil, handle for extraction of permanent intravenous and subcutaneous leads.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2006-10-03** Date: **2019-03-12** Expiry Date: **2021-10-02**

...making excellence a habit.™

DICHIARAZIONE CE DI CONFORMITÀ in accordo alla Direttiva 93/42/CEE
EC DECLARATION OF CONFORMITY according to 93/42/EEC Directive

(Rif./*Ref.* NQ-04-01)

Vicchio, 23 Dicembre 2019
Vicchio, 23 December 2019

La società FIAB SpA, con sede in via P. Costoli, 4 - 50039 Vicchio (FI),
nella persona dell' Amministratore Delegato Alberto Calabrò,
FIAB SpA having its headquarters at 50039 Vicchio (FI), Via P. Costoli 4,
in the person of Managing Director Alberto Calabrò,

dichiara, sotto la propria responsabilità, che i dispositivi
declares, under its own responsibility, that the devices

maschere per ossigenoterapia a concentrazione media, modelli:
medium concentration masks for oxygen therapy, models:

OS/100, OS/100P, OS/100N, OS/100T, OS/100A-30

inclusi nel Master File MF 101 */ part of Master File MF 101*

sono conformi ai requisiti della Direttiva 93/42/CEE (DLgs. 46/97) e successive modifiche,
comply with the requirements of 93/42/EEC Directive, including amendments,

appartengono alla Classe IIa / *are Class IIa products,*

codice GMDN **35171**,
codice CND **R03010201**,

non contengono sostanze medicinali né elementi di origine animale,
do not contain drug substances or elements of animal origin,

che è stata seguita la procedura per la valutazione della conformità descritta in Allegato V della suddetta direttiva,
that FIAB has followed the conformity assessment procedure described in Annex V of the above-mentioned directive,

come riportato sul certificato CE n°CE 510679 rilasciato da British Standard Institution (O.N. n°2797),
as described in the EC Certificate No.CE 510679 issued by British Standard Institution (N.B. No. 2797),

che sono state seguite le procedure di gestione del sistema di qualità FIAB secondo ISO 13485,
Certificato di Registrazione n°MD 77846 rilasciato da BSI,
that the procedures of FIAB quality system management according to ISO 13485 have been followed,
Certificate of Registration No.MD 77846 issued by BSI,

che sono state applicate, tra le altre, le seguenti norme armonizzate:
that, among the others, the following standards were applied:

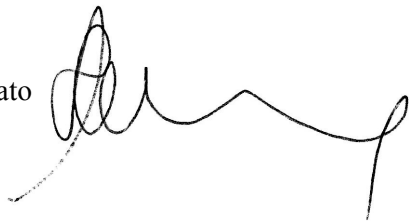
EN ISO 15223-1, 2016 - EN ISO 14971, 2012 - EN ISO 10993-1, 2009 - EN 1041, 2008 - EN ISO 13544-2, 2002+A1:2009 - EN 15986:2011

e che non contengono lattice / *and that they are Latex-free*

CE009/101

Prima emissione/*First Issued:* 18/05/2006
Ultima revisione/*Last Issued:* 23/12/2019

FIAB SpA
Amministratore Delegato
Managing Director
Alberto Calabrò



FIAB SpA – Sede legale: Via P. Costoli, 4 – 50039 VICCHIO – Firenze – Italia
Unità operative: Via Passerini, 2, 4,6 / Via della Resistenza, 18 – 50039 VICCHIO – Firenze – Italia
Tel. +39 0558497999 – FAX +39 0558497979 – www.fiab.it
Cap. Soc. Int. Vers. 500.000 € - C.F.-P.I e n. Reg. Imp. FI 01835220482 – Trib. FI n.33541 – C.C.I.A.A. FI n. 339066 REA – c/c postale 14476501 EUROPEAN VAT: IT 01835220482

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел/факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы паровой стерилизации химические одноразовые «ИНТЕСТ-П-«ВИНАР» по ТУ 9398-041-11764404-2003

Регистрационное удостоверение
№ РЗН 2013/39
от 27.08.2019 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н18061
от 24.06.2019 г.

Модификация : ***«ИНТЕСТ-П-121/20-02»***

Партия *9130109* ***Дата изготовления*** *Октябрь 2019 г.*

Гарантийный срок *3 года*
Условия эксплуатации и хранения *в соответствии с инструкцией производителя*
Код ОКПД 2 32.50.50.190

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-041-11764404-2003	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный
за контроль качества
М.П.

ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

ЧУВАНОВА А. А.

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел/факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы химические одноразовые воздушной стерилизации МедИС-В-Винар по ТУ 9398-032-11764404-2004

Регистрационное удостоверение
№ ФСР 2009/05017
от 27.08.2019 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н18087
от 18.09.2019 г.

Модификация : ***«МедИС-В-180/60»***

Партия ***9177109*** ***Дата изготовления*** ***Октябрь 2019 г.***

Гарантийный срок ***3 года***
Условия эксплуатации и хранения ***в соответствии с инструкцией производителя***
Код ОКПД 2 32.50.50.190

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-032-11764404-2004	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный
за контроль качества Чуванова А. А.

М.П. ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31701101

Zavet Company Subsidiary

04136, Severo-Syretska St, 3, Kyiv, UKRAINE

ISO 13485:2016

Design, Manufacturing, Sales and Service of Medical Stretchers, Medical Beds, Medical Chairs and Eye Charts

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	11.07.2017
Issue Date	26.12.2019
Expiry Date	25.12.2022
Revision Date/No	26.12.2019 / 5

IAS ACCREDITED Management Systems Certification Body

Deputy General Manager

The certificate inquiry is made by reading QR Code by mobile devices or providing necessary information on http://public.szutest.com.tr.