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

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.28 11:20:58 EEST
Reason: MoldSign Signature
Location: Moldova

IMQ

cosign

IMQ 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

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-030

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

NÜVE SANAYİ MALZEMELERİ
İMALAT ve TİCARET ANONİM ŞİRKETİ

Saracalar Mahallesi Saracalar Kümeevleri No:4/2 Akyurt Ankara, Turkey

Products: Steam Sterilizers, Dry Heat Sterilizers, Blood Bank Refrigerators, Deep Freezers, Platelet Incubators

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.3158.10
Date of first issue:	31 May 2010
Date of last issue:	19 February 2019
Revision Number:	08
Expiry Date:	18 February 2024

19 February 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

HPi Verification Services

EU-type Examination Certificate

This is to certify that the product listed below conforms to the requirements of the

Pressure Equipment Directive 2014/68/EU

Annex III Module B(prod)

Certificate Number	HPiVS/P1057-048-I-01 rev.1
Date of Issue	15-Nov-2017 **Date of Expiry** 01-Oct-2027
Designer	**NÜVE SANAYİ MALZEMLERİ İMALAT VE TİCARET A.Ş.** Saracalar Mah. Saracalar Kümeevleri No:4/2 Akyurt /Ankara /Turkey
Description of Pressure Equipment	Steam sterilizer Range : NC 23B, NC23S, NC32S, NC 100, NC 150, NC 150D, NC 40M, NC 90M, NC 300, NC 430, NC 430D, NC 570, NC 570D, NC 710, NC 710D; Steam generator Range: NC 100, NC 150, NC 300, NC 430, NC 570, NC 710.
Drawing No	N 8467, N 8466, N 8468, N 8475, N 8458, N 8460, N 8463, N 8462, N 8464, N 8461, N 8465, N 7118, N 8040, N 8036, N 6871, N 7987, N 8457, N 7539, N 8359, N 8456 Rev.0 dated 28 Sep 2017; N 8515 Rev.0 dated 19 Oct 2017; N 8497 Rev.0 dated 05 Oct 2017; N 8491 Rev.0 dated 26 Sep 2017
Serial No	n/a
Design Pressure	PS = 3 bar (for NC 23S, NC 23B, NC 32S PS = 2,6 bar)
Design Temperature	Max 144 °C (for NC 23S, NC 23B, NC 32S Max 140 °C)
Standards Used	EN 13445
Report Reference	HPiVS/P1057-048-DR01 to DR04

This Certificate is valid in any European Economic Area Member State.

This Certificate has been issued by HPi Verification Services Ltd which is a body notified to the European Commission according to the provisions of the Pressure Equipment Directive (Notified Body number 1521).

This Certificate is issued following the assessment of a representative sample of the Pressure Equipment detailed above in accordance with the provisions of the above regulations. The equipment must be subject to an appropriate conformity assessment module during manufacture prior to the CE Mark being affixed.

Check this certificate is genuine

Managing Director

Technical Manager

EU Notified Body No. 1521
Company registered in England #7217086

Tel +44 1491 822818
Fax +44 700 600 6831
Email enquiries@eucertification.com
www.eucertification.com

HPi Verification Services Ltd.
The Manor House
Howbery Park, Wallingford
OX10 8BA, United Kingdom

ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Italia

CERTIFICATO

Nr. 50 100 5990/A Rev.005

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

FAZZINI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

STRADA STATALE PADANA SUPERIORE 317

IT - 20090 VIMODRONE (MI)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

VEDI **ALLEGATO 1**

*SEE **ANNEX 1***

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*

Dal / From: **2021-11-29**

Al / To: **2024-06-14**

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione /
Issuing Date

2021-11-29

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-07-02

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2021-06-14
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2021-06-14

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 5990/A Rev.005**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 5990/A Rev.005***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 5990/A Rev.005 È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE:
THE CERTIFICATE N 50 100 5990/A Rev.005 IS VALID FOR THE FOLLOWING SCOPE:

Progettazione, gestione della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi attivi chirurgici (aspiratori chirurgici), dispositivi non attivi per terapia intensiva (aspiratori chirurgici manuali), dispositivi attivi per la respirazione (aerosol) e loro accessori. Gestione della progettazione e della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi non attivi con funzione di misura (sfigmomanometri, bilance), dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (palloni, accessori per respirazione, anestesia ed aerosolterapia, immobilizzatori, laringoscopi endotracheali, set di pronto soccorso, barelle), dispositivi non attivi ortopedici e per la riabilitazione (ausili per disabili e riabilitazione), strumenti chirurgici non attivi, strumenti chirurgici attivi (elettrobisturi), dispositivi non attivi (dispositivi ospedalieri ed ambulatoriali per il supporto e la movimentazione del paziente e accessori, stetoscopi), dispositivi attivi non impiantabili e relativi accessori e di dispositivi attivi per monitoraggio (elettrocardiografi, pulsossimetri, monitor, bilance). Commercializzazione e assistenza post vendita di dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (accessori per respirazione ed anestesia, accessori per medicazioni e per prelievi), dispositivi attivi per il posizionamento ed il trasporto del paziente (tavoli operatori), dispositivi attivi per la respirazione (accessori per respirazione), dispositivi attivi per la disinfezione e sterilizzazione (sterilizzatrici), dispositivi per l'elettrochirurgia, la stimolazione o l'inibizione (stimolatori), dispositivi non attivi con funzione di misura (termometri), di dispositivi attivi per monitoraggio (termometri, misuratori di pressione) e di arredi per ufficio (IAF 19, 29)

Design, manufacturing management, trade and after sales service of active surgical devices (suction pumps), non-active devices for intensive care (manual suction pumps), active devices for breathing therapy (aerosol) and their accessories. Management of design and manufacture, trade and after sales service of non-active devices with a measuring function (blood pressure monitors, scales), non-active devices for anesthesia, emergency and intensive care (balloons, accessories for breathing, anesthesia and aerosol therapy, immobilizers, laryngoscopes endotracheal, first aid kit, stretchers), non-active devices for orthopedic and rehabilitation (aids for the disabled and rehabilitation), non-active devices surgical instruments, active surgical instruments (electrocautery), non-active devices (devices for hospital and ambulatory for the support and the movement of the patient and accessories, stethoscopes), active non implantable device and related accessories and of active devices for monitoring (electrocardiographs, pulse oximeters, monitors, scales). Trade and after sales service of non-active devices for anesthesia, emergency and intensive care (accessories for breathing and anesthesia, dressing and accessories for withdrawals), active devices for positioning and patient support (operating tables), active devices for respiration (breathing accessories), active devices for disinfection and sterilization (sterilizers), devices for electrosurgery, stimulation or inhibition (stimulators), non-active devices with a measuring function (thermometers), active devices for monitoring (thermometers, blood pressure monitors) and office furnitures (IAF 19, 29)

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*
Dal / From: **2021-11-29**
Al / To: **2024-06-14**

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione / *Issuing Date*
2021-11-29

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-07-02

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2021-06-14
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-06-14*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ CERTIFICATE

Italia

CERTIFICATO

Nr. 50 100 5990/B Rev.008

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

FAZZINI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

STRADA STATALE PADANA SUPERIORE 317

IT - 20090 VIMODRONE (MI)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI CEI EN ISO 13485:2016

SISTEMI QUALITÀ – DISPOSITIVI MEDICALI
QUALITY SYSTEMS – MEDICAL DEVICES

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

VEDI **ALLEGATO 1**

*SEE **ANNEX 1***

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità / *Validity*

Dal / From: **2021-11-29**

Al / To: **2024-06-14**

Data emissione / *Issuing Date*

2021-11-29

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-07-02

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE 2021-06-14
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-06-14*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 5990/B Rev.008**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 5990/B Rev.008***

IL CERTIFICATO NR 50 100 5990/B Rev.008 È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE:
THE CERTIFICATE N 50 100 5990/B Rev.008 IS VALID FOR THE FOLLOWING SCOPE:

Progettazione, gestione della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi attivi chirurgici (aspiratori chirurgici), dispositivi non attivi per terapia intensiva (aspiratori chirurgici manuali), dispositivi attivi per la respirazione (aerosol) e loro accessori. Gestione della progettazione e della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi non attivi con funzione di misura (sfigmomanometri, bilance), dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (palloni, accessori per respirazione, anestesia ed aerosolterapia, immobilizzatori, laringoscopi endotracheali, set di pronto soccorso, barelle), dispositivi non attivi ortopedici e per la riabilitazione (ausili per disabili e riabilitazione), strumenti chirurgici non attivi, strumenti chirurgici attivi (elettrobisturi), dispositivi non attivi (dispositivi ospedalieri ed ambulatoriali per il supporto e la movimentazione del paziente e accessori, stetoscopi), dispositivi attivi non impiantabili e relativi accessori. Gestione della progettazione e della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi attivi per monitoraggio (elettrocardiografi, pulsossimetri, monitor, bilance). Commercializzazione e assistenza post vendita di dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (accessori per respirazione ed anestesia, accessori per medicazioni e per prelievi), dispositivi attivi per il posizionamento ed il trasporto del paziente (tavoli operatori), dispositivi attivi per la respirazione (accessori per respirazione), dispositivi attivi per la disinfezione e sterilizzazione (sterilizzatrici), dispositivi attivi per monitoraggio (termometri, misuratori di pressione), dispositivi per l'elettrochirurgia, la stimolazione o l'inibizione (stimolatori), dispositivi non attivi con funzione di misura (termometri)

Design, manufacturing management, trade and after sales service of active surgical devices (suction pumps), non-active devices for intensive care (manual suction pumps), active devices for breathing therapy (aerosol) and their accessories. Management of design and manufacture, trade and after sales service of non-active devices with a measuring function (blood pressure monitors, scales), non-active devices for anesthesia, emergency and intensive care (balloons, accessories for breathing, anesthesia and aerosol therapy, immobilizers, laryngoscopes endotracheal, first aid kit, stretchers), non-active devices for orthopedic and rehabilitation (aids for the disabled and rehabilitation), non-active surgical instruments, active surgical instruments (electrocautery), non-active devices (devices for hospitals and ambulatory for the support and movement of the patient and accessories, stethoscopes), non-active implantable devices and related accessories. Management of design and manufacture, marketing and after sales service of active devices for monitoring (electrocardiographs, pulse oximeters, monitors, scales). Trade and after sales service of non-active devices for anesthesia, emergency and intensive care (accessories for breathing and anesthesia, dressings and accessories for withdrawals), active devices for positioning and patient transport (operating tables) , active devices for respiration (breathing accessories), active devices for disinfection and sterilization (sterilizers), active devices for monitoring (thermometers, blood pressure monitors), devices for electrosurgery, stimulation or inhibition (stimulators), non active devices with a measuring function (thermometers)

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*
Dal / From: **2021-11-29**
Al / To: **2024-06-14**

SGQ N° 049A

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

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione / *Issuing Date*
2021-11-29

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-07-02

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2021-06-14
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-06-14*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-030

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

NÜVE SANAYİ MALZEMELERİ
İMALAT ve TİCARET ANONİM ŞİRKETİ

Saracalar Mahallesi Saracalar Kümeevleri No:4/2 Akyurt Ankara, Turkey

Products: Steam Sterilizers, Dry Heat Sterilizers, Blood Bank Refrigerators, Deep Freezers, Platelet Incubators

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.3158.10
Date of first issue:	31 May 2010
Date of last issue:	19 February 2019
Revision Number:	08
Expiry Date:	18 February 2024

19 February 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

HPi Verification Services

EU-type Examination Certificate

This is to certify that the product listed below conforms to the requirements of the

Pressure Equipment Directive 2014/68/EU

Annex III Module B(prod)

Certificate Number	HPiVS/P1057-048-I-01 rev.1
Date of Issue	15-Nov-2017 **Date of Expiry** 01-Oct-2027
Designer	**NÜVE SANAYİ MALZEMLERİ İMALAT VE TİCARET A.Ş.** Saracalar Mah. Saracalar Kümeevleri No:4/2 Akyurt /Ankara /Turkey
Description of Pressure Equipment	Steam sterilizer Range : NC 23B, NC23S, NC32S, NC 100, NC 150, NC 150D, NC 40M, NC 90M, NC 300, NC 430, NC 430D, NC 570, NC 570D, NC 710, NC 710D; Steam generator Range: NC 100, NC 150, NC 300, NC 430, NC 570, NC 710.
Drawing No	N 8467, N 8466, N 8468, N 8475, N 8458, N 8460, N 8463, N 8462, N 8464, N 8461, N 8465, N 7118, N 8040, N 8036, N 6871, N 7987, N 8457, N 7539, N 8359, N 8456 Rev.0 dated 28 Sep 2017; N 8515 Rev.0 dated 19 Oct 2017; N 8497 Rev.0 dated 05 Oct 2017; N 8491 Rev.0 dated 26 Sep 2017
Serial No	n/a
Design Pressure	PS = 3 bar (for NC 23S, NC 23B, NC 32S PS = 2,6 bar)
Design Temperature	Max 144 °C (for NC 23S, NC 23B, NC 32S Max 140 °C)
Standards Used	EN 13445
Report Reference	HPiVS/P1057-048-DR01 to DR04

This Certificate is valid in any European Economic Area Member State.

This Certificate has been issued by HPi Verification Services Ltd which is a body notified to the European Commission according to the provisions of the Pressure Equipment Directive (Notified Body number 1521).

This Certificate is issued following the assessment of a representative sample of the Pressure Equipment detailed above in accordance with the provisions of the above regulations. The equipment must be subject to an appropriate conformity assessment module during manufacture prior to the CE Mark being affixed.

Check this certificate is genuine

Managing Director

Technical Manager

EU Notified Body No. 1521
Company registered in England #7217086

Tel +44 1491 822818
Fax +44 700 600 6831
Email enquiries@eucertification.com
www.eucertification.com

HPi Verification Services Ltd.
The Manor House
Howbery Park, Wallingford
OX10 8BA, United Kingdom

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Fazzini s.r.l.
SS Padana Sup. 317
20090 Vimodrone (MI)
ITALIA

Product Service

Add value.
Inspire trust.

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
Daniele Dipinto	PS-MHS-CRT	mhs-crt@tuev-sued.de	+49 89 50084-327	2020-04-03	1 of 2

Distribution of Certificates in Electronic Format due to the Special Circumstances of the Corona Crisis

Dear Certificate Holder / Manufacturer

The Corona Crisis is confronting TÜV SÜD with new challenges. For this reasons many of our employees are working from home office in order to support the measures of the government intended limit the spread of the COVID 19 virus as far as possible.

For you as TÜV SÜD customer nothing changes. As usual we are available for you and all certificates are issued. But considering the circumstances, it is not possible to distribute the in paper form as usual.

For this reason, you hereby receive a PDF of the certificate. Compared to the established approach no certificate paper is used.

We hereby submit the following certificates in PDF format:

- G1 044963 0034 Rev. 01 ENGLISH
- G1 044963 0034 Rev. 01 ITALIAN
- G3M 044963 0032 Rev. 01 ENGLISH
- G3M 044963 0032 Rev. 01 ITALIAN
- G3M 044963 0031 Rev. 01 ENGLISH
- G3M 044963 0031 Rev. 01 ITALIAN

Product Service

The aforementioned certificates were issued and released according to the applicable process of the of the certification body / notified body TÜV SÜD Product Service GmbH.
The certificates are issued to the certificate holder / manufacturer:

Fazzini s.r.l.
SS Padana Sup. 317
20090 Vimodrone (MI)
ITALIA

They are valid to the full extent. Validity can be verified via the TÜV SÜD Certificate Explorer by scanning the QR code on the PDFs. The full scope statement is available on the PDFs provided.

EC or EU certificates may be used for placing on the market of medical devices with CE0123 according to the requirements of the applicable medical device legislation. Certificates and test marks may only be used considering the test and certification regulation of TÜV SÜD which can be found under www.tuev-sued.com/ps_regulations.

As soon as the special situation of the corona virus has settled down and normal office operations is possible again you will receive paper copies of all certificates.

Yours sincerely,
i.A.
Roman Braun
Roman Braun (Apr 3, 2020)

Electronic Signature Information

Name	DOC2024286
Revision	1
Type	Controlled Document
Title	9100c NXT DOC
Originator	100035647_shlomi__deler
Release Date	08/30/2017 07:25:36 AM
Obsolete Date	

File Name	File Description	File Size (Bytes)
9100cNXT EU Declaration of Conformity_DOC2024286_29.AUG.2017.pdf	9100c NXT DoC	272432

Route	Signer	Function	Status	Comments	Completion Date
R-8844209	100035647_shlomi__deler		Approve	Approved by RA Directiror	30 Aug 2017 07:24:57 GMT

Periodic Review

There are no signatures or routes related to this business object.

Obsolesence Approval

There are no signatures or routes related to this business object.

* Printed versions are For Reference Only *
+ Indicates a task was reassigned from an original assignee

Released

GE Healthcare

EC Declaration of Conformity

(Following the provisions of the medical devices directive 93/42/EEC and of the directive 2011/65/EU)

Manufacturer:

GE Medical Systems (China) Co., Ltd
No.19, Changjiang Road,
Wuxi National Hi-Tech Dev. Zone
214028, Jiangsu, China

Authorized EU Representative

GE Medical systems SCS
283 Rue de la Minière,
78530 BUC,
FRANCE

We hereby declare under our sole responsibility that the class IIb product:

Product Name: **9100c NXT** [including accessories and components]
GMDN Code: **37710**
UMDNS Code: **10-134**
Classification rule (rule 11 acc. to Annex IX of the Directive 93/42/EEC): IIb

to which this declaration relates is in conformity with the essential requirements which apply to it (annex II of the medical devices directive 93/42/EEC). In addition, the product is in conformity with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as assessed by the manufacturer).

This conformity is based on the following elements:

- Information included in the Technical Documentation DOC2024285 of the product to which this declaration relates
- EC Certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by TÜV Rheinland LGA Products GmbH, Notified Body #0197, Certificate N° HD 60116081 0001
- List of harmonized standards applied for CE marking is in the technical documentation file for this product

29 AUG 2017

Monica Morrison
Regulatory Affairs Director

Date

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems

Replaces certificate, registration no.: HD 60137935 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification includes the following manufacturing sites:

No.	Location
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland
/03	Hamilton Medical AG Parc Industrial Vial 4 7013 Domat/Ems Switzerland

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Bevollmächtigter

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

Certificate Holder: **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
Switzerland

including the locations according to annex

Scope: Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-09 until 2023-07-08.
First certification 2017

2021-01-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

No.	Location	Scope
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development and distribution of ventilators and ventilator systems
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing of ventilators and ventilator systems
/03	Hamilton Medical UK Ltd. Unit 1 Forge Mills Park Station Road Coleshill Birmingham B46 1JH United Kingdom	Distribution and servicing of ventilators and ventilator systems

2021-01-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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