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: 2021.02.10 10:43:05 EET
Reason: MoldSign Signature
Location: Moldova

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

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

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

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

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

MINISTERUL SĂNĂTĂŢII, MUNCII
ŞI PROTECŢIEI SOCIALE
AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ, ТРУДА
И СОЦИАЛЬНОЙ ЗАЩИТЫ РЕСПУБЛИКИ МОЛДОВА
AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, mun. Chişinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: ansp@ansp.md; anticamera@ansp.md

DOCUMENTAŢIE MEDICALĂ / Медицинская документация
FORMULAR / Форма **Nr. 303-2/e**
APROBAT DE MSMPS al RM / Утверждена МЗТСЗ РМ
31.10.11 Nr. 828
Centrul de încercări de laborator acreditat de către
Centrul Naţional de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный
Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LÎ-044 din 17.02.2018 valabil până la 16.02.2022
Acreditat în Sistemul Ministerului Sănătăţii, Muncii
şi Protecţiei Sociale al RM
Аккредитованный в системе Министерства Здравоохранения, Труда и
Социальной Защиты Республики Молдова
Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR

PENTRU PRODUSELE ALIMENTARE ŞI NEALIMENTARE Nr. P-2363/2019

Санитарное заключение для пищевых и непищевых продуктов

din/*от* " 31 " iulie a./*г.* 2019

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Cutii din carton

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / *указать полное наименование санитарного (ых) регламента (ов)*

HG nr.308 din 29.04.2011 „ Regulamentul sanitar privind materialele şi obiectele destinate să vină în contact cu produsele alimentare", SM GOST R 52354:2006

Organizaţia-producătoare/importatoare, ţara de origine / *организация произв./импортер, страна происхождения*

Ucraina, ООО "ДУНАПАК ТАВРИЯ"

Destinatarul avizului sanitar / *получатель санитарного заключения*

„ATGAIA-SU" SRL, Moldova, Chişinău, bd.Dacia, 19, ap.11

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) a servit / *Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило*

Demers, contract nr.TA 000384 din 11.03.2014, facturi, certificat de calitate, conformitate, raport a încercărilor de laborator nr.4360 din 29.07.2019, din 24.07.2019
(a enumera documentele de însoţire, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)*	**Normativul sanitar** / *санитарный норматив*
conform raportului încercărilor de laborator nr.4360 din 29.07.2019, din 24.07.2019	

Domeniu de utilizare / *Область применения:* ambalaj, inclusiv produse alimentare

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*

importul, plasarea pe piaţă în condiţiile respectării legislaţiei în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 30 iulie 2020

DIRECTORUL AGENŢIEI NAŢIONALE PENTRU SĂNĂTATE PUBLICĂ
Int. Nicolae FURTUNĂ
(numele, prenumele/ Ф.И.О.) (semnătura / подпись)

L.Ş. ANSP/HAO3

SP 10-XVI-09 0004963 O3

ex:Şt.Constantinovici
tel: 574 679

VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi / disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".

"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *"Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60119814 0001

Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products:
Products for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60076687 0001

Expiry Date: 2022-05-28

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC 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 IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2017-05-29

Date: 2017-05-29

Notified Body

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60119814 0001
Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products for self-testing:
- Single and multi-parameter disposable test strips for urine analysis
- indicator test strips and papers for measurement of pH in urine

Additional site for warehousing and logistics:

Bahnstr. 120
52355 Düren, Germany

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2017-05-29

Dipl.-Ing. Sven Hoffmann

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

CERTIFICATE

Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C

CERTIFICATE

Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		
Previous expiry date			

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

SGQ N° 007A

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization:
MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

Scope:
Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28

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125 DS 02 Q
Ind 7 – juin 16

Organisme accrédité COFRAC N° 4-0023
Accredited body by COFRAC N° 4-0023

AB certification

CERTIFICAT
CERTIFICATE

N° A 3001

Nous certifions par la présente que le Système de Management de la Qualité de la société :
We hereby certify that the Quality Management System of the company:

BIOLABO
LES HAUTES RIVES
02160 Maizy - France

est conforme aux exigences de la norme suivante :
is in compliance with the requirements of the following standard:

ISO 9001 : 2015

Le domaine d'application du Système de Management de la Qualité est le suivant :
The scope of the Quality Management System is:

CONCEPTION, FABRICATION ET VENTE DE DISPOSITIFS MÉDICAUX DE DIAGNOSTIC IN VITRO. SUPPORT TECHNIQUE ET SERVICE D'ASSISTANCE.

DESIGN, MANUFACTURING AND SALE OF IN VITRO DIAGNOSTIC MEDICAL DEVICES. TECHNICAL SUPPORT AND SUPPORT SERVICES.

Ce certificat demeurera en vigueur jusqu'à sa fin de validité à moins d'avis contraire, à condition que la mise en place et la conformité du Système du Management de la Qualité soient jugées satisfaisantes lors des audits de surveillance et que les conditions du contrat de AB Certification soient observées.
This certificate is valid until its expiry date unless further notice, provided that the compliance and implementation of the Quality Management System are found to be satisfactory at follow-up audits and that AB Certification contract rules are fulfilled.

Fait à PARIS, le 24 décembre 2018
Signed in PARIS on the 24th of December 2018

Date de validité : 23 décembre 2021
Expiry date: 23rd of December 2021

Georges ABI RACHED
Le Représentant d'AB Certification
AB Certification Representative

Le Représentant de l'Entreprise
The Company Representative

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation N°4-0023
PORTÉE DISPONIBLE SUR www.cofrac.fr

Ce certificat est la propriété d'AB Certification. Il devra lui être retourné en cas de demande. AB Certification – 19, rue de Paradis – 75010 PARIS

125 DS 02 M16
Ind 0 juin 17

Organisme accrédité COFRAC N° 4-0023
Accredited body by COFRAC N° 4-0023

CERTIFICAT
CERTIFICATE

N°A 3001

Nous certifions par la présente que le Système de Management de la Qualité des Dispositifs Médicaux de la société :
We hereby certify that the Medical Devices Quality Management System of the company:

BIOLABO
LES HAUTES RIVES
02160 Maizy - France

est conforme aux exigences de la norme suivante :
is in compliance with the requirements of the following standard:

ISO 13485 : 2016

Le domaine d'application du Système de Management de la Qualité des Dispositifs Médicaux est le suivant :
The scope of the Medical Devices Quality Management System is as follows:

CONCEPTION, FABRICATION ET VENTE DE DISPOSITIFS MÉDICAUX DE DIAGNOSTIC IN VITRO. SUPPORT TECHNIQUE ET SERVICE D'ASSISTANCE.

DESIGN, MANUFACTURING AND SALE OF IN VITRO DIAGNOSTIC MEDICAL DEVICES. TECHNICAL SUPPORT AND SUPPORT SERVICES

Ce certificat demeurera en vigueur pour une période de trois ans à moins d'avis contraire, à condition que la mise en place et la conformité du Système du Management de la Qualité des Dispositifs Médicaux soient jugées satisfaisantes lors des audits de surveillance et que les conditions du contrat de AB Certification soient observées.
This certificate is valid for a three-year period unless further notice, provided that the compliance and implementation of the Medical Devices Quality Management System are found to be satisfactory at follow-up audits and that AB Certification contract rules are fulfilled.

Fait à PARIS, le 24 décembre 2018
Signed in PARIS on the 24th of December 2018

Date de validité : 23 décembre 2021
Expiry date: 23rd of December 2021

Georges ABI RACHED
Le Représentant d'AB Certification
AB Certification Representative

Le Représentant de l'Entreprise
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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

has established and applies a quality management system for medical devices for the following scope:

Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-10-16
Certificate Registration No.:	SX 60133221 0001
An audit was performed. Report No.:	21234760 009
This Certificate is valid until:	2021-10-15

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-10-12

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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EC Certificate

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

Registration No.: HD 60150763 0001

Report No.: 21234760 013

Manufacturer:

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products:

- Cannulas for blood collection
- MBU Capillaries
(see attachment for details)

Replaces certificate, Registration No.: HD 60105393 0001

Expiry Date: 2024-05-26

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.

Notified Body

Effective Date: 2020-10-07

Date: 2020-10-07

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60150763 0001
Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- MBU Capillaries

Notified Body

Date: 2020-10-07

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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www.imq.it

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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*:
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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