CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

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 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 e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I 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 and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

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

Digitally signed by Ceaicovschi Tudor
Date: 2024.06.13 13:14:24 EEST
Reason: MoldSign Signature
Location: Moldova

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	2023-10-24	2026-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A

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

ITALCERT

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

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 13485-2021 (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 e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I 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 and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

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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	2023-10-24	2026-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

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

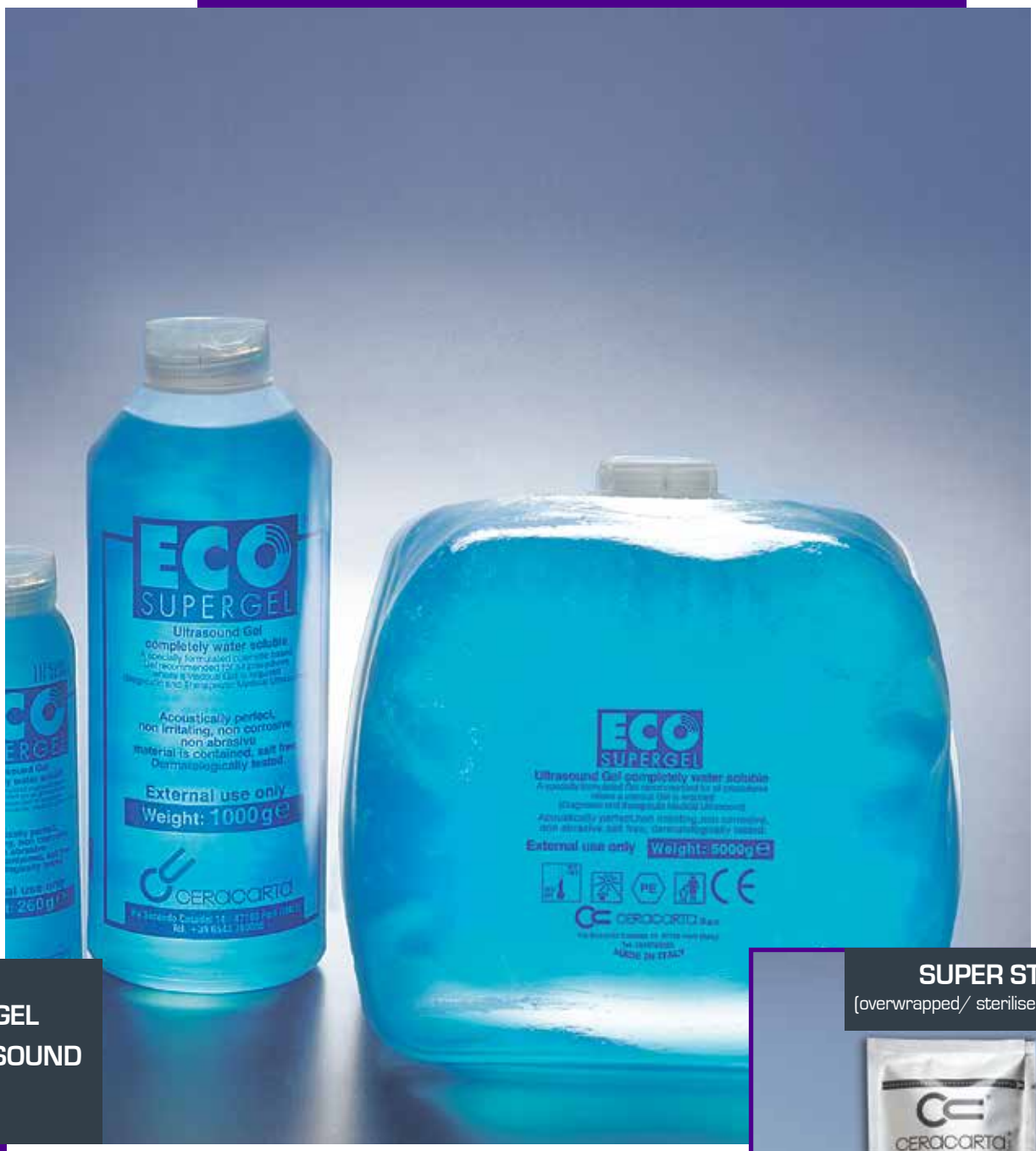
ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

GELS & CREAMS

Superior quality

Ceracarta produces Gels for ultrasound, for ECG and for EEG whose quality can without any doubt be defined as superior. The results obtained in this field come from a detailed research, combined with several decades' experience as well as continuous tests and trials in laboratories and in the most modern hospitals. All this has convinced even the most demanding users that the reliability of Ceracarta Supergels is unbeatable and its products are regarded among the best found on the market today.

CE CERACARTA
MADE IN ITALY



ECO SUPERGEL FOR ULTRASOUND

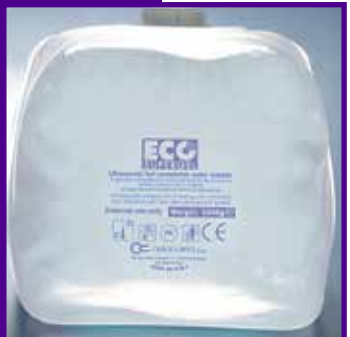
ECO SUPERGEL FOR ULTRASOUND

The carefully designed composition of this gel means that it is particularly suitable for diagnostic exams and ultrasound treatments.

- No salt is contained to prevent damaging the probes
- It does not cause skin irritation even after many scans
- Excellent viscosity (80,000 RPM5-STD 18°)
- Rapid transmission speed (1.48)
- Perfect acoustic impedance
- Extremely efficient
- Bacteriostatic levels lower than admissible even by the most stringent international standards

AVAILABLE IN THREE VERSIONS:

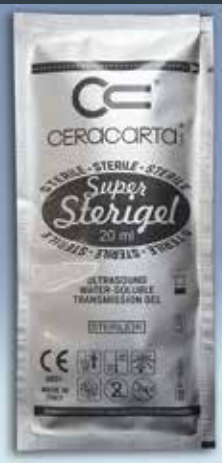
- **260 g. (box with 25 bottles)**
- **1 l. (box with 8 bottles)**
- **5 kg. (individual pack with bottle/refill - box with 4 pieces).**



Available in "CLEAR" version too!

SUPER STERIGEL

(overwrapped/ sterilised foil pouch)



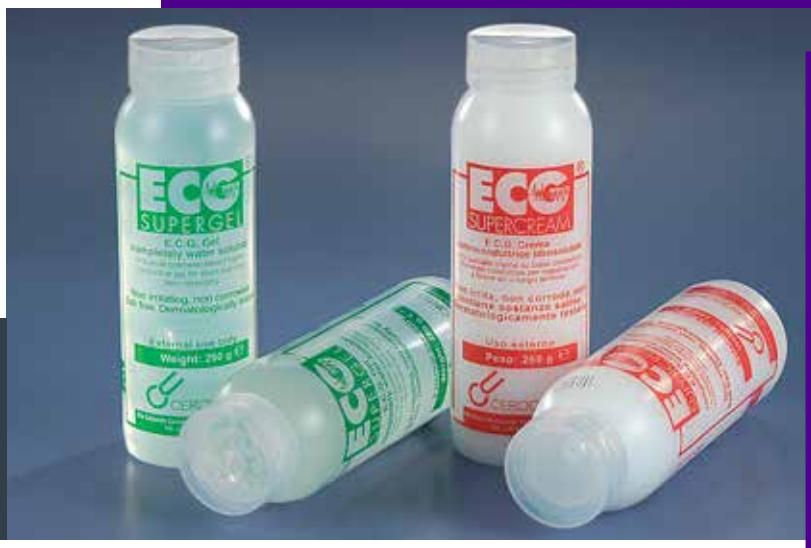
SUPER STERIGEL

It keeps unaltered its characteristics of functionality, efficiency, reliability and transparency even after sterilisation process has ended up. It ensures absolute sterility as a guarantee for the peculiar applications it is intended for, such as:

- when a biopsy or puncture is being performed;
- when mucous membranes are involved;
- when scanning non-intact skin or close to fresh surgical wounds;
- when treating babies/newborns, having high sensitive skins.

Excellent transmission of the signal to obtain high-resolution images.

ECO SUPERGEL & SUPERCREAM

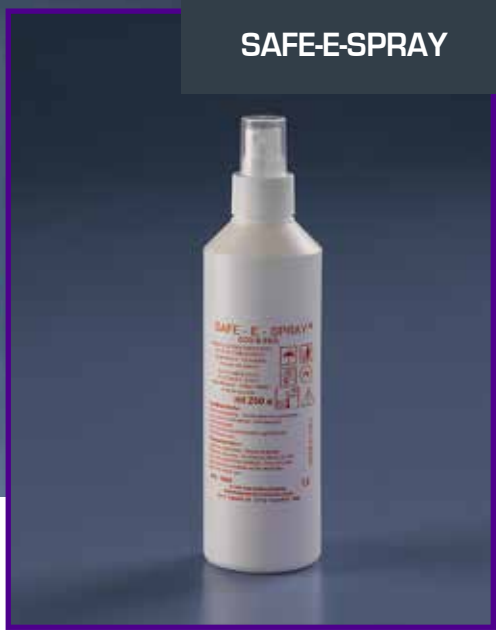


ECG SUPERGEL & SUPERCREAM

In order to obtain high quality ECG recordings for a long time it is essential to have a really "super" gel. The composition studied for the gel or for the cream (same characteristics, but with a lightly perfumed cosmetic base) actually allows for an improvement of the signal, preventing any kind of anomaly and providing users with a constantly reliable monitoring.

- No salt contained
- It does not damage the electrodes it comes into contact with
- Soluble in water
- It does not irritate even the most delicate skin types
- Not greasy
- Optimal viscosity
- Bacteriostatic levels lower than admissible even by the most stringent international standards
- PP-HDPE 260 g. container with total guarantee (box with 25 bottles).

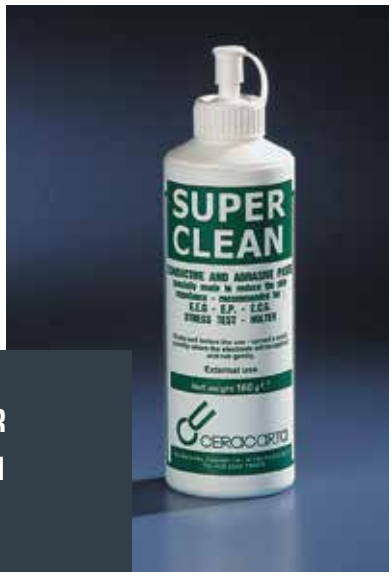
SAFE-E-SPRAY



SAFE-E-SPRAY /ECG & EEG

An absolutely practical spray to obtain the best possible conductivity during ECG/EEG monitoring. It strengthens the performance of the electrodes, by removing the bacteria and the dirt gathered on the surface. This product is recommended for preparing the skin before examination. Hypoallergenic, water soluble, antibacterial, odourless, non-greasy, does not stain. Packing: 250 ml. bottle ; n°25 bottles/box.

SUPER CLEAN



SUPER CLEAN

Degreasing paste apt for skin cleansing before EEG-EP-ECG recordings. Allowing to reduce impedence down to minimum levels when a signal devoid of any adulteration is needed.

- Water-based, viscous gel
- Colouring agents free, non-irritating
- 160 g. PLTHD-PLTLD bottle (24 pcs per box).

EEG/EMG SUPERCREAM & PASTE

EEG SUPERCREAM

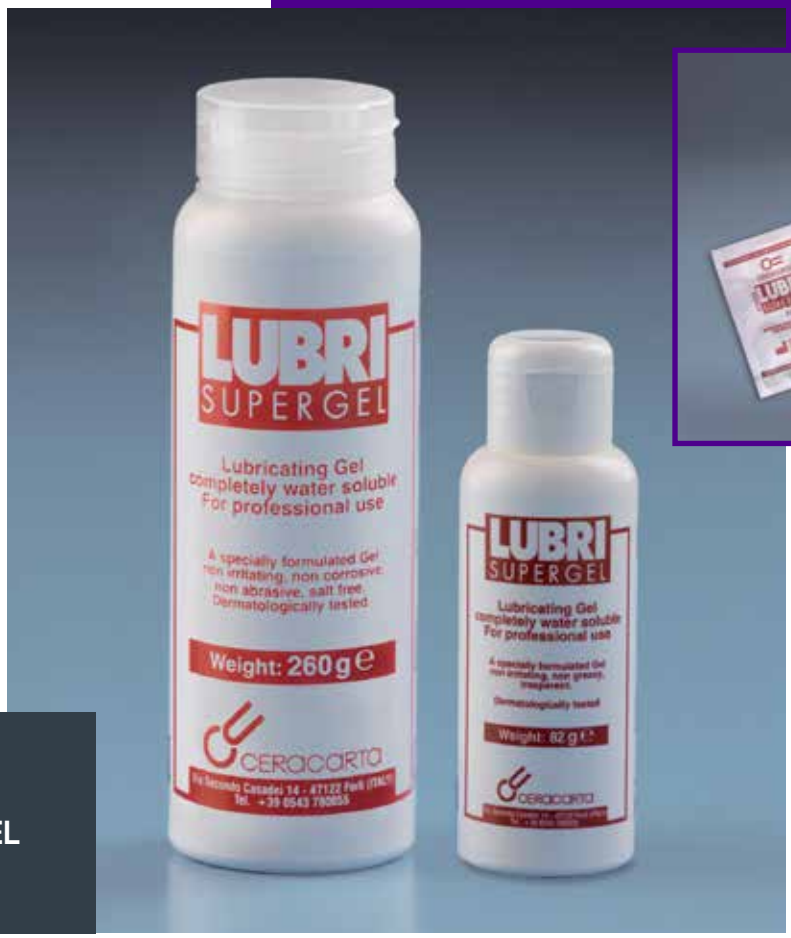
Water-soluble and highly conductive cream for EEG-EP-EMG recordings.

- Non-irritating, non-greasy
- Non-damaging the probes
- 260 g. PP-HDPE bottle (25 pcs per box).

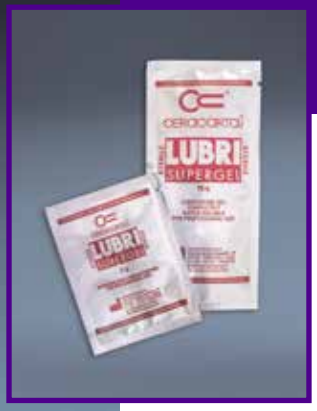
EEG PASTE "SUPERIOR QUALITY"

Highly adhesive & above-average conductive paste, suitable for disc electrodes.

- Pale white colour
- Water-soluble
- PH from 6.6 to 7
- Low impedance
- 250 g. jar (24 pieces per carton).



LUBRI SUPERGEL



STERILE VERSION AVAILABLE!
(5 g. and 15 g. pouch)

LUBRI SUPERGEL
Lubricant gel for both professional and family use.
Thanks to its ingredients, this gel is the best for endoscopy, gastroscopy, colonscopy, proctoscopy and, more in general, for all those domestic applications that do not need a sterile product. Hypoallergenic, non-irritant, non-toxic, odourless, water soluble.

Packing:
- 82 g. bottle ; n°48 bottles/box
- 260 g. bottle ; n°25 bottles/box.

AQUASONIC PARKER

CUSTOMISED GELS

AQUASONIC – PARKER
Ceracarta is the official distributor of this gel for ultrasound famous all over the world. The quality and characteristics of this gel are undoubtedly excellent. Available in three versions:
• 250 g. (box with 12 bottles - carton with 72 pieces) • 5 kg (individual package with bottle/refill - box with 4 pieces) • 20 g. Sterile gel in a small metal bag wrapped inside another sealed bag - guaranteed (48 pieces per box).

CUSTOMISED GELS
Ceracarta can provide solutions for important customers who, for any reason, might require a customised gel packaging. At no extra cost you can have bottles or containers graphically designed to meet each customer's taste and requirements.

CE 0051
class I MD > class I MD (incl. Im)

ISO 14001 ISO 45001

CE CERACARTA MADE IN ITALY

Company registered with US FDA

ISO 9001:2015

EN ISO 13485:2016

Via Secondo Casadei N.14
zona industriale Villa Selva - 47122 Forlì (Italy) tel. +39.0543.780055 - fax +39.0543.781404
www.ceracarta.it - e mail: export@ceracarta.it

REV.10/2021

DECLARATION OF CONFORMITY

Forlì, 19th April 2012

The device named " ECG SUPERGEL" (internal code 10158) has been produced by the company Ceracarta Spa on the basis of the essential requirements,see enclosure I of the directive 93/42/CEE,as prescribed in attachment VII of the above directive.
The writing company Ceracarta located in Via secondo Casadei , 14 Forlì, manufacturer of the product named , " ECG SUPERGEL ", declares under its own responsability that such a device satisfies all the requirements of directive 93/42/CEE as amended by 2007/47/EC , about medical devices and in particular that:

- the Dispositive in object satisfies the essential requirements as in enclosure I of Directive 93/42/CEE;
- the Dispositive in object must be considered as belonging to Class I;
- the Dispositive in object must be esclusively used together with electro-medical instruments for recording, diagnosis and therapy, which base their functioning upon the measuring of energy flows of electric, magnetic and ultrasound type;
- The manufacturer has prepared and keeps the technical files updated in accordance with enclosure VII, section 3 of the directive itself.
- Such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.

CERACARTA spa
IL PRESIDENTE
Marino Bandini

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

www.imq.it

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

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

CERACARTA SPA

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

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI 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. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

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

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo 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

CISQ

www.cisq.com

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

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

www.imq.it

ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

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

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

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

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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CISQ

www.cisq.com

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CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

www.imq.it

ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

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

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

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

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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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IQNET

Building trust together.

Certificate

CISQ/IMQ has issued an IQNET recognized certificate that the organization:

CERACARTA SPA

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

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

has implemented and maintains a
Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

which fulfils the requirements of the following standard:
ISO 9001:2015

Issued on: **2023/10/04**
Expires on: **2026/10/07**

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

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

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

IQNET Members*:
AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic **Cro Cert** Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC** Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifiointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

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

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

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 No.

4265/5/D

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

VACUTEST KIMA S.r.l.

Sede / *Head office*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Uffici direzionali e amministrativi
Unità Operative / *Operative Units*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.
Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)
Uffici commerciali e magazzino.

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

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CISQ is the Italian Federation of management system Certification Bodies.

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INSTRUCTIONS FOR USE

L.E.S. LATEX

LATEX AGGLUTINATION SLIDE TEST FOR THE DETERMINATION OF ANTI-N-DNA ANTIBODIES ASSOCIATED WITH SYSTEMIC LUPUS ERYTHEMATOSUS (S.L.E.)

1 – CLINICAL SIGNIFICANCE AND INTENDED USE

For ***in Vitro*** diagnostic use only

Systemic lupus erythematosus (SLE) is a chronic inflammatory disease of unknown cause that affects multiple organ systems (articulations, skin, kidneys, central nervous system, heart, lungs). Immunologic abnormalities, especially the production of a number of antinuclear antibodies (ANA), are another prominent feature of this disease. The clinical course is marked by spontaneous remissions and relapses. Its multisystemic manifestations and the complications from the use of immunosuppressive agents make the diagnosis and management of this entity challenging. The detection of ANA antibodies by laboratory methods include immunofluorescence, LE Cells test and agglutination of coated latex particles. These antibodies anti-DNP are believed to cause the formation of the LE cell in vitro, with this unusual event occurring in 75-80% of those patients diagnosed as having SLE. Some patients having symptoms suggestive for SLE had been found negative with LE Cells Test. In these individuals, ANA antibodies may be demonstrated by methods other than the LE cell test, as latex agglutination or immunofluorescence.

L.E.S. LATEX is a rapid agglutination procedure, developed for the direct detection and the semi-quantitation on a slide of antideoxyribonucleoprotein antibodies (anti-DNP) in human serum.

2 - PRINCIPLE OF THE METHOD

The assay is performed by testing a suspension of latex particles coated with DNP against unknown serums. The presence or absence of a visible agglutination indicates the presence or absence of anti-DNP antibodies in the samples tested.

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
L.E.S. LATEX CND: W0102100116 EDMA: 12.10.01.16; RDM: 1555421/R	Latex agglutination test	**UB80800** (62 tests)	1 glass bottle containing latex for L.E.S., suspension of polystyrene latex particles coated with DNP (calf thymus) in a buffered solution. Contain Sodium azide < 0.1% (3,1 mL = 62 tests) 1 glass bottle containing Positive Control: human serum with anti-DNP activity. Contain Sodium azide < 0.1% (0.5 mL) 1 glass bottle containing Negative Control: stabilized liquid control, contain Sodium azide < 0.1% (0,5 mL) Slide, 6 test areas: plastic waterproof sheets for reaction (11 items) Sticks (1x25): plastic sticks for mixing (3 items) Secondary packaging: cardboard box.
L.E.S. CONTROLLI CND: W0102100116 EDMA: 12.50.01.13; RDM: 1555441/R	Controls for latex agglutination test	**UD80802** (2x0,5 mL)	1 glass bottle containing Positive Control: human serum with anti-DNP activity. Contain Sodium azide <0.1% (0.5 mL) 1 glass bottle containing Negative Control: stabilized liquid control, contain Sodium azide <0.1% (0,5 mL) Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Mechanical rotator with adjustable speed at 80-100 r.p.m. Timer or clock. Pipettes. Saline solution (9 g/L NaCl, only for semi-quantitation procedure).

5 - PRECAUTIONS AND WARNINGS

- L.E.S. LATEX is a kit for in vitro diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel.
- Components of human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
- The sensitivity of the test may be reduced at low temperatures. Allow the reagents and samples to reach room temperature (15-30ºC/59-86ºF) before use to have best results.
- Do not use after expiration date or if the packaging is damaged. The quality of the reagent cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state, provincial or national regulations. Refer to Material Safety Data Sheet for any updated risk, hazard or safety information.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.masciabrunelli.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.
- Notify Mascia Brunelli Spa and the Relevant Authorities of any serious incidents occurring in connection with the in vitro diagnostic device. complaint@masciabrunelli.it

6 - STORAGE CONDITIONS AND SHELF LIFE

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Mix reagents gently before use.

Reagents deterioration: Presence of particles and turbidity in controls; don't use it. Bacterial contamination of reagents or specimens may cause false positive results.

7 – SPECIMENS COLLECTION

Fresh, clear serum. Stable 7 days at 2-8ºC or 3 months at –20ºC. Do not use highly hemolysed or lipemic samples.

8 - TEST PROCEDURE

Allow the components of the kit to reach to room temperature (15-30ºC/59-86ºF) prior to testing.

Qualitative test

1. Gently shake the suspension for homogenization of the latex particles.

2. Always use positive and negative controls as references.
3. Place **30 µL of the serum** under test into one of the circles on the slide. Dispense **1 drop of each Positive and Negative control** into two additional circles.
4. Add **1 drop or 40 µL of Latex reagent** to each circle next to the sample to be tested (serum, positive and negative control).
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide, either manually or with a mechanical stirrer 80 to 100 rpm for **1 minute***.
7. Observe the presence or absence of visible agglutination immediately.

**Samples giving indeterminate results may be retested increasing the rotation period to 2 minutes. Reaction times longer that 2 minutes might cause false positive results.*

Semiquantitative test

For each specimen to be tested place with a pipette 30 µl of saline solution (NaCl 9 g/L) into each of the 6 circles of a slide.
To circle one add 30 µl of specimen to the saline solution and, using the same tip, mix the saline solution with the sample by repeated aspiration and expulsion of the fluid and transfer 30 µl of the mixture to the saline solution in the second circle.
Continue with the 2-fold serial dilutions in a similar manner up to the sixth circle, and discard 30 µl from this circle. Final sample dilutions will be: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64.
Test each dilution as described in steps 4-7 for the Qualitative Test.

9 – READING, INTERPRETATION AND CALCULATION

Qualitative test: Nonreactive: smooth suspension with no visible agglutination, as shown by negative control.
Reactive: any degree of agglutination visible macroscopically.

Semiquantitative tests: same as Qualitative test. The titer is defined as the highest dilution showing reactivity. The next higher dilution should be negative.

10 – QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation. All result different from the negative control result, will be considered as a positive.

11- EXPECTED VALUES

A positive result indicates the level of anti-deoxyribonucleoprotein antibodies (DNP) is in the range commonly found in systemic lupus erythematosus.

12 – CHARACTERISTICS

Analytical performance. Serum samples were tested with L.E.S. LATEX : 29 had active SLE, 23 had clinically inactive SLE, 8 had connective tissue diseases and the remaining 95 were clinically normal or had some nonrelated diseases (anemia, infectious mononucleosis and rheumatic diseases). Results were compared with a standard LE Cell preparation assay and a fluorescent ANA method.

	Found	L.E.S. TEST Mascia Brunelli	LE Cell Preparation	F-ANA Test	Total
Active SLE	Positive	24 83%	25 86%	24 83%	29
Inactive SLE	Positive	4 17.4%	4 17.4%	16 70%	23
Connective tissue diseases	Positive	0 0%	1 12.5%	4 50%	8
Clinically normal/non related diseases	Positive	1 1%	1 1%	6 6%	95

13 – LIMITATIONS OF THE METHOD

- Serum from patients with scleroma, rheumatoid arthritis, dermatomyositis and a variety of connective tissue diseases may elicit agglutination in the L.E.S. Test.
- As high levels of antibodies might affect the degree of agglutination, positive samples should be re-assayed using semi-quantitative procedure.
- Plasma samples should not be used because of the possibility of non-specific results.
- Bacterial contamination of controls and specimens as well as freezing and thawing of the L.E.S. TEST reagent may lead to false positive results.
- Drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce an SLE syndrome.
- As with all diagnostic tests, a final diagnosis cannot rely on the outcome of a single test and must be supported by other clinical and laboratory data.
- The components of this I.v.D. were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.

14 – REFERENCES

1. Cristian CL, Mendez-Byran R, Larson DL. Proc Exp Biol Med, 1958; 98: 820-823.
2. Friou GJ, Finch SC, Detre KD. J Immunol 1958; 80: 324-329.
3. Hargraves MM, Richmond H, Morton R. Proc Mayo Clin 1948; 23: 25-28
4. Holman HR, Kunkel HG, Science 1957; 126: 263
5. Miescher PA, Strassel R. Vox Sang 1957; 2: 283-287
6. Miescher PA, Rothfield N, Miesher A. Lupus Erythematosus 1966; EL Dubois, Ed., Blakiston Co., New York
7. Rothfield NF, Thythyon JJ, McEwan C, Miescher P. Arth Rheuma 1961; 4: 223-229.
8. Young, D.S. Effects of Drugs on Clinical Laboratory Tests. 4th Edition. AACC Press (1995).

TABLE OF APPLICABLE SYMBOLS

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (DXXX)		Manufacturer		Keep dry	UDI	Unique device identifier
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 3	Updated layout and content	2022/10

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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Certified Quality System
ISO 13485:2021
Cert. n° D1016000050
ISO 9001:2015
Cert. n° D1016000051
ISO 14001:2015
Cert. n° AQS/A/104412023

DICHIARAZIONE CE DI CONFORMITA'

In accordo all' allegato III della Direttiva 98/79/EC
dispositivi medico-diagnostici in vitro

Si certifica che i prodotti IVD presenti nell'elenco allegato sono fabbricati da Mascia Brunelli SpA.

1. Rispettare i requisiti essenziali (Allegato I) della Direttiva IVD 98/79 / CE. Questa conformità è adeguatamente documentata e rispetta tutti i requisiti elencati nell'Allegato I della suddetta Direttiva.

2. Il sottoscritto dichiara che sono adempiuti gli obblighi imposti dall'Allegato III commi da 2 a 5:
- La disponibilità della documentazione tecnica di cui all'allegato III (sezione 3), che consente la valutazione della conformità dei prodotti ai requisiti della direttiva.
- Il produttore adotta tutte le misure necessarie per garantire che il processo di fabbricazione segua il principio di garanzia della qualità appropriato per i prodotti fabbricati (allegato III sezione 4).
- Il produttore ha istituito e mantenuto aggiornata una procedura sistematica per il riesame post-produzione dei dispositivi in vitro e si impegna ad applicare le azioni correttive (Allegato II sezione 5).

3. Mascia Brunelli SpA dispone di un Sistema di Qualità certificato secondo le norme EN ISO 9001 e EN ISO 13485.

4. La presente dichiarazione di conformità certifica che i requisiti dell'allegato I e dell'allegato III sono rispettati e documentati.

5. Mascia Brunelli SpA dichiara che la documentazione tecnica di cui all'allegato III della suddetta Direttiva è disponibile presso i nostri uffici e da noi conservata per cinque anni dall'ultimo lotto di produzione.

6. Validità: il presente documento è valido per cinque anni e sarà aggiornato su base annuale

7. Questi prodotti (vedere allegato) sono stati marcati CE come altro dispositivo medico IVD nell'Allegato II in quanto non rientrano né nell'elenco A e B dell'allegato II della Direttiva 98/79 / CE, né nei prodotti di classe A in accordo al Regolamento Europeo 746/2017 (IVDR).

Mascia Brunelli SpA conferma che nessun farmaco o medicinale è incluso nei prodotti elencati.

Dr.ssa Beatrice Brunelli
MASCIA BRUNELLI Spa

Milano, 30/11/2023

Dichiarazione CE rev. 31 30/11/2023

All: 1

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Certified Quality System
ISO 13485:2021
Cert. n° D1016000050
ISO 9001:2015
Cert. n° D1016000051
ISO 14001:2015
Cert. n° AQS/A/104412023

DECLARATION OF CONFORMITY

According to Annex III of the IVD Medical Device Directive 98/79/EC

This is to certify the IVD products in the attached list are manufactured by Mascia Brunelli SpA.

1. Comply with the essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the above Directive.

2. The undersigned declares that the obligations imposed by Annex III sections 2 to 5 are fulfilled:
   - The availability of the technical documentation as set out in Annex III (section 3), allowing the assessment of conformity of the products with the requirements of the directive.
   - The manufacturer takes all necessary measures to ensure that the manufacturing process follows the principle of quality assurance as appropriate for the products manufactured (Annex III section 4).
   - The manufacturer has instituted and kept up to date a systematic procedure to review experience gained from devices in the post-production phase and implements appropriate means to apply corrective actions (Annex II section 5).

3. Mascia Brunelli SpA has certified Quality System in place to the EN ISO 9001 and EN ISO 13485 standard.

4. This Declaration of Conformity certifies that the requirements of Annex I and Annex III have been met and documented.

5. Mascia Brunelli SpA declares that the technical documentation as for Annex III of the above mentioned Directive is available in our offices and we be kept for five years since last production batch

6. Validity: this document is valid for five years and will be revised yearly basis

7. These products (please see attachment) have been CE Marked as other IVD Medical Device to Annex II as they neither be part of the products in List A or B of the Annex II of the Directive 98/79/EC neither in class A according to European Regulation 746/2017 (IVDR).

Mascia Brunelli SpA confirms that no drug or medicine is included in the listed products.

Dr.ssa Beatrice Brunelli
MASCIA BRUNELLI Spa

Milano, 30/11/2023

CE-Declaration Rev. 31
30rd November 2023

Annex: 1

Allegato / Annex 1
Mascia Brunelli Catalogo Generale/General Catalog - 2021-2022

Prodotto/Product	Codice/Ref
DIAGNOSTICA RAPIDA: TEST IMMUNOCROMATOGRAFICI	
RAPID DIAGNOSTIC TESTS: LATERAL FLOW TESTS	
ADENO+ROTA COMBI DIPSTICK	VC1004
ADENO RESPI CARD	VC1014
ADENO RESPI CARD PLUS	VC1014P
ADENO+ROTA CARD	VC194025
ADENO+ROTA CARD PLUS	VC194025P
ADENOVIRUS CARD	VC194020
ADENOVIRUS CARD PLUS	VC194020P
ASTROVIRUS - DIPSTICK	VC1020
ASTROVIRUS - DIPSTICK PLUS	VC1020P
ß-HCG MONOSTEP TEST	VP80417
ß-HCG MONOSTEP TEST PLUS	VP80417P
BENCE JONES KAPPA & LAMBDA FREE DIPSTICK	VT83000
BUPRENORFINA CARD	VU86101
BUPRENORFINA CARD	VU86110
CALPROTECTIN CARD	VT81610
CALPROTECTIN 50-200 CARD	VT81615
CAMPYLOBACTER SPECIES Ag CARD	VC1007
CAMPYLOBACTER SPECIES Ag CARD PLUS	VC1007P
CLOSTRIDIUM DIFFICILE GDH	VC194065
CLOSTRIDIUM DIFFICILE GDH CARD PLUS	VC194065P
CLOSTRIDIUM DIFFICILE TOXIN A + B	VC194055
CLOSTRIDIUM DIFFICILE TOXIN A + B PLUS	VC194055P
COCAINA CARD	VU85401
COCAINA CARD	VU85410
COMBI GDH-TOX A+B	VC194070P
CRYPTO+GIARDIA CARD	VC1023P
CRYPTO-DIPSTICK	VC1005
CRYPTO-DIPSTICK PLUS	VC1005P
COMBI GASTROENTEROVIRUS CARD	VC194026
COMBI GASTROENTEROVIRUS CARD PLUS	VC194026P
CRYPTO+GIARDIA+ENTAMEBA CARD	VC1032
DENGUE COMBO NS1+ IgG/IgM	VQ84006
DROGHE MULTI TEST CARD 7 parametri	VU85007
DROGHE MULTI TEST CARD 10 parametri	VU85010
E.COLI O157 CARD	VC1010
E.COLI O157 CARD PLUS	VC1010P
ENTAMOEBA Ag CARD	VC1030
ENTEROVIRUS	VC1026
ENTEROVIRUS PLUS	VC1026P

Prodotto/Product	Codice/Ref
GARDNERELLA VAGINALIS	VQ81601
GIARDIA CARD	VC1016
GIARDIA CARD PLUS	VC1016P
GONORREA Ag CARD	VQ81602
HANTAAN IgG / IgM CARD	VQ84008
HAV IgM/IgG CARD	VR82006
Hb FECALE	VT81510
Hb FECALE PLUS	VT81520
Hb-FECAL-TRANSFERRIN COMBI	VT81650
HELICOBACTER PYLORI CARD Ab	VQ81650
HEPY STOOL CARD	VT82000
HEPY STOOL CARD	VT82001
HEPY STOOL CARD PLUS	VT82001P
HEPY STOOL CARD PLUS	VT82003P
HEPYLORI	VC1150
HEPYLORI PLUS	VC1150P
iGFBP-1 RAPID TEST KIT	VP86000
INFLUENZA A+B-RESPI-DIPSTICK	VC1012
INFLUENZA A+B-RESPI-DIPSTICK PLUS	VC1012P
LACTOFERRIN CARD	VT81600
LEGIONELLA PNEUMOPHILA CARD	VQ84100
LEGIONELLA PNEUMOPHILA CARD PLUS	VQ84100P
LEISHMANIA Ab CARD	VQ85210
LEPTOSPIRA CARD	VQ85100
MALARIA MBPan	VQ81706
MALARIA MBPan PLUS	VQ81706P
MICROALBUMINA MONOSTEP	VT81802
MONONUCLEOSI CARD IgM	VQ82705
MONONUCLEOSI CARD PLUS IgM	VQ82705P
NOROVIRUS	VC1027
NOROVIRUS CARD PLUS	VC1027P
OPPIACEI (EROINA-MORFIN-CODEINA) CARD	VU85301
OPPIACEI (EROINA-MORFIN-CODEINA) CARD	VU85310
ROTA DIPSTICK	VC1001
ROTAVIRUS CARD	VC194022
ROTAVIRUS CARD PLUS	VC194022P
RSV+ADENO-RESPI-DIPSTICK	VC1019
RSV-RESPI-CARD	VC1015
RSV-RESPI-CARD PLUS	VC1015P
SALMONELLA Ag	VQ84060
STREP B CARD	VQ81305
STREP B CARD	VQ81310
STREP B CARD PLUS	VQ81310P
STREP A CARD	VQ81209
STREP A CARD	VQ81210
STREP A CARD PLUS	VQ81210P

Prodotto/Product	Codice/Ref
STREP PNEUMONIAE	VQ84070P
SYPHILIS Ab	VQ83000
TRICHOMONAS VAGINALIS	VQ81604
TUBERCULOSI	VQ81800
DIAGNOSTICA RAPIDA: TEST IN AGGLUTINAZIONE	
RAPID TESTS: AGGLUTINATION TESTS	
ASO LATEX	UA80300
ASO LATEX	UA80315
CAMPYLOBACTER RAPID LATEX TEST KIT	271020
E. COLI O157 RAPID LATEX TEST KIT	271080
LEGIONELLA RAPID LATEX TEST KIT - KIT COMPLETO	271050
LEGIONELLA LATEX TEST 01	271051
LEGIONELLA LATEX TEST 2-15	271052
LEGIONELLA LATEX SPP TEST	271053
LEGIONELLA LATEX TEST KIT PLUS	271054
LUPUS ERYTEMATOSUS SISTEMICO (L.E.S.) LATEX	UB80800
MONONUCLEOSI LATEX	UB80710
MONONUCLEOSI LATEX	UB80720
PCR LATEX	UA80100
PCR LATEX	UA80110
RF LATEX	UA80200
RF LATEX	UA80210
RPR TEST	UC80600
RPR TEST	UC80610A
SALMONELLA RAPID LATEX TEST KIT	271030
STAPH RAPID LATEX TEST KIT	271060
STREP GROUPING RAPID LATEX TEST KIT	271070
STREP GROUPING RAPID LATEX TEST KIT	271071
STREP GROUPING RAPID LATEX TEST KIT	271072
TPHA TEST	UC80500
TPHA TEST	UC80515
WAALER-ROSE TEST	UA80255
CONTROLLI PER TEST RAPIDI	
LATERAL FLOW and AGGLUTINATION CONTROLS	
ADENOVIRUS CONTROLLI	UD80015
ASO CONTROLLI	UD80320
BENCE JONES CONTROLLI	QA20100B
Calprotectin CONTROLLI	UD80050
CLOSTRIDIUM DIFFICILE Tox. A+B CONTROLLI	UD80360
CRYPTOSPORIDIUM CONTROLLI	UD80360
GIARDIA CONTROLLI	UD80041

Prodotto/Product	Codice/Ref
EMOGLOBINA (Hb FECALE) CONTROLLI	UD80010
HELICOBACTER PYLORI CONTROLLI	UD80005
LEGIONELLA PNEUMOPHILA CONTROLLI	UD80035
LUPUS ERYTEMATOSUS SISTEMIC (L.E.S.) CONTROLLI LATEX	UD80802
MONONUCLEOSI CONTROLLI	UD80700
PCR CONTROLLI	UD80120
RF CONTROLLI	UD80220
ROTAVIRUS CONTROLLI	UD80020
RSV CONTROLLI	UD80040
STREP A CONTROLLI	UD80025
STREP B CONTROLLI	UD80030
TPHA CONTROLLI	UD80502
WAALER-ROSE CONTROLLI	UD80252
CHIMICA CLINICA	
CLINICAL CHEMISTRY	
ACE (Angiotensin Converting Enzyme)	NACE8865
ACE CALIBRATORE	ACECAL8865
ACIDI BILIARI	NABIL8903
ACIDI BILIARI CONTROLLI	NABIL8901
ACIDO CITRICO	NCI8822
ADA (Adenosine Deaminase)	NCADA016
ADA CONTROLLO	NCADAC01
ALDOLASE	ZZALD100
AMMONIA	NAAM8870
CALCULUS ANALYSIS III	3914003
CI+OX CALIBRATORE ACIDO CITRICO e OSSALATI	CTOG111
FRUTTOSIO-GLUCOSIO	NCGF8815
G6PDH CONTROL SET	NAG6CON
G6PDH-CALIBRATOR	NAG6CAL3
G6PDH-GLUCOSE 6 PHOSPHATE DEHYDROGENASE	NAGP68905
G6PDH-RED CELL LYSING REAGENT	NAGB1129
G6PDH-GLUCOSE 6 PHOSPHATE DEHYDROGENASE SET	NAG6P8910
L- LACTIC ACID	NALA8810
OSSALATI	NAOX8850
OXALATE PURIFIER	NAOXA75
OXALATE CONTROLLO ALTO	OG6502
OXALATE CONTROLLO BASSO	OG6627
PYRUVATE	NAPY8825
PYRUVATE KINASE	NCPK8831
PYRUVATE KINASE (PK) CONTROL 4X1mL	OGPKC032
RAME	NB12000
SUBSTRATE ELEVATED CONTROL	OG3005
SUBSTRATE LOW CONTROL	OG3006

Prodotto/Product	Codice/Ref
TOTAL HEMOGLOBIN	NATHEMO395
UREA INSTANT TEST	NCURE900
VMA	340249000
ZINCO	NB12100
TURBIDIMETRIA: PROTEINE URINARIE ***TURBIDIMETRY: URINARY PROTEINS***	
PROTEINURIA DI BENCE JONES (BENCE JONES PROTEINS	QA20100
BENCE JONES CONTROLLI	QA20100B
SIEROLOGIA BATTERICA ***FEBRILE ANTIGENS***	
FEVER MACROTEST (3 x 20 ml = 120 TEST)	
SALMONELLA TYPHI H	XA100000
SALMONELLA TYPHI O	XA100100
SALMONELLA TYPHI TOTALE	XA100050
SALMONELLA PARATYPHI AH	XA100200
SALMONELLA PARATYPHI AO	XA100300
SALMONELLA PARATYPHI A TOTAL	XA100250
SALMONELLA PARATYPHI BH	XA100400
SALMONELLA PARATYPHI BO	XA100500
SALMONELLA PARATYPHI B TOTAL	XA100450
SALMONELLA PARATYPHI CH	XA100600
SALMONELLA PARATYPHI CO	XA100700
SALMONELLA PARATYPHI C TOTAL	XA100650
BRUCELLA (TOTAL)	XA100800
BRUCELLA ABORTUS	XA100850
BRUCELLA MELITENSIS	XA100860
BRUCELLA SUIS	XA100870
PROTEUS OX 19	XA100900
PROTEUS OX 2	XA101000
PROTEUS OX K	XA101100
SALMONELLA ENTERITIDIS TOTAL	XA101250
LISTERIA KIT TUBE TEST	XA87249
LISTERIA CONTROLLI POSITIVO E NEGATIVO	XE105050
FEVER MICROTEST (3 x 10 ml = 300 TEST)	
SALMONELLA TYPHI H	XB100001
SALMONELLA TYPHI O	XB100101
SALMONELLA TYPHI TOTAL	XB100051
SALMONELLA PARATYPHI AH	XB100201
SALMONELLA PARATYPHI AO	XB100301
SALMONELLA PARATYPHI A TOTAL	XB100251

Prodotto/Product	Codice/Ref
SALMONELLA PARATYPHI BH	XB100401
SALMONELLA PARATYPHI BO	XB100501
SALMONELLA PARATYPHI B TOTAL	XB100451
SALMONELLA PARATYPHI CH	XB100601
SALMONELLA PARATYPHI CO	XB100701
SALMONELLA PARATYPHI C TOTAL	XB100651
BRUCELLA (TOTAL)	XB100801
BRUCELLA ABORTUS	XB100851
BRUCELLA MELITENSIS	XB100861
BRUCELLA SUIS	XB100871
PROTEUS OX 19	XB100901
PROTEUS OX 2	XB101001
PROTEUS OX K	XB101101
SALMONELLA ENTERITIDIS TOTAL	XB101211
FEVER KIT	XB105000
FEVER KIT MINOR	XB105550
FEVER SLIDE TEST (1 x 5 ml = 125 TEST)	
SALMONELLA TYPHI H	XC100002
SALMONELLA TYPHI O	XC100102
SALMONELLA TYPHI TOTAL	XC100052
SALMONELLA PARATYPHI AH	XC100202
SALMONELLA PARATYPHI AO	XC100302
SALMONELLA PARATYPHI A TOTAL	XC101252
SALMONELLA PARATYPHI BH	XC100402
SALMONELLA PARATYPHI BO	XC100502
SALMONELLA PARATYPHI B TOTAL	XC101452
SALMONELLA PARATYPHI CH	XC100602
SALMONELLA PARATYPHI CO	XC100702
SALMONELLA PARATYPHI C TOTAL	XC101652
BRUCELLA (TOTAL)	XC100802
BRUCELLA "BENGAL ROSE"	XC100852
BRUCELLA ABORTUS	XC100842
BRUCELLA MELITENSIS	XC100862
PROTEUS OX 19	XC100902
PROTEUS OX 2	XC101002
PROTEUS OX K	XC101102
MULTIBACTERIAL KIT	XC105100
SALMONELLA TYPHI H	XC100002B
SALMONELLA TYPHI O	XC100102B
SALMONELLA PARATYPHI AH	XC100202B
SALMONELLA PARATYPHI AO	XC100302B
SALMONELLA PARATYPHI A TOTAL	XC101252B
SALMONELLA PARATYPHI BH	XC100402B
SALMONELLA PARATYPHI BO	XC100502B
SALMONELLA PARATYPHI B TOTAL	XC101452B

Prodotto/Product	Codice/Ref
SALMONELLA PARATYPHI CH	XC100602B
SALMONELLA PARATYPHI CO	XC100702B
SALMONELLA PARATYPHI C TOTAL	XC101652B
BRUCELLA ABORTUS	XC100842B
BRUCELLA MELITENSIS	XC100862B
FEVER QUICK TEST (1 x 5 ml = 125 TEST)	
SALMONELLA TYPHI H	XD100003
SALMONELLA TYPHI O	XD100103
SALMONELLA PARATYPHI AH	XD100203
SALMONELLA PARATYPHI AO	XD100303
SALMONELLA PARATYPHI A TOTAL	XD100253
SALMONELLA PARATYPHI BH	XD100403
SALMONELLA PARATYPHI BO	XD100503
SALMONELLA PARATYPHI B TOTAL	XD100453
SALMONELLA PARATYPHI CH	XD100603
SALMONELLA PARATYPHI CO	XD100703
SALMONELLA PARATYPHI C TOTAL	XD101653
BRUCELLA (TOTAL)	XD100803
BRUCELLA ABORTUS	XD100843
BRUCELLA MELITENSIS	XD100863
BRUCELLA SUIS	XD100873
PROTEUS OX 19	XD100903
PROTEUS OX 2	XD101003
PROTEUS OX K	XD101103
MULTIBACTERIAL QUICK TEST KIT	XD105003
SIERI DI CONTROLLO ***CONTROL SERA***	
CONTROLLO NEGATIVO	XE105030
CONTROLLO POSITIVO POLIVALENTE	XE105040
REAGENTI PER AGGREGAZIONE PIASTRINICA ***PLATELET AGGREGATION***	
AGP TEST	3115001
ADP 0,1 mM	311501A
ADENOSIN DIFOSFATO (ADP) 0,1 mM	311500AC
ADP 1 mM	311500WA
ADRENALINE 5mM (Epinephrin) LIO	311501BL
ADRENALINA 5 mM	311500BLC
ARACHIDONIC ACID (25 mM)	311501WB
ARACHIDONIC ACID (25 mM)	311501WBC
COLLAGEN 1 mg/ml	311502C
COLLAGENE 1 g/l	311501CC
RISTOCETIN 25 mg	311502D

Prodotto/Product	Codice/Ref
RISTOCETINA 25 mg	311500DC
TRAP-6 1 mM	311500T

NovaTec Immundiagnostica GmbH

Product List – CE Marked

Certified by

ISO 13485:2016

EC – Directive 98 / 79 EC
For In-Vitro-Diagnostics

2020-02-1

NovaTec Immundiagnostica GmbH

NovaLisa® Virology

Prod. No.	Name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM µ-capture
CMVG0110	Cytomegalovirus (CMV) IgG
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM µ-capture
NS1D4020	Dengue Virus NS1 Antigen
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVM0250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simples Virus 1 (HSV 1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFM0290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFM0300	Influenza Virus B IgM
MEAG0330	Measles Virus IgG
AMEA7330	Avidity Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B 19 IgG
PARM0370	Parvovirus B 19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG

ARUB7400	Avidity Rubella Virus IgG
RUBM0400	Rubella Virus IgM µ-capture
TICG0440	TBE / FSME IgG
TICM0440	TBE / FSME IgM
PTICG044	TBE / FSME IgG plus
VZVA0490	Varicella-Zoster Virus (VZV) IgA
VZVG0490	Varicella-Zoster Virus (VZV) IgG
VZVM0490	Varicella-Zoster Virus (VZV) IgM
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Bacteriology

Prod. No.	Name
BAR0900	Bartonella
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM

MYCA0350	Mycoplasma pneumoniae IgA
MYCG0350	Mycoplasma pneumoniae IgG
MYCM0350	Mycoplasma pneumoniae IgM
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus

NovaLisa ® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TOXM0460	Toxoplasma gondii IgM µ-capture

NovaLisa ® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa ® Fungi

Prod. No.	Name
ASPG0680	Aspergillus fumigatus IgG
ASPM0680	Aspergillus fumigatus IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM

NovaLisa ® Hormones

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
FT41050	Free T4
TSH1030	TSH

Hormones

STEROID HORMONES
(ELISAs for the determination of steroid hormones in plasma and serum)

Prod. No.	Name
DNOV001	Cortisol
DNOV002	Testosterone
DNOV003	17 beta-Estradiol
DNOV004	17-OH Progesterone
DNOV005	DHEA-S
DNOV006	Progesterone
DNOV008	Androstenedione
DNOV009	Free Testosterone
DNOV011	Total Estriol
DNOV012	Aldosterone

STEROID HORMONES IN URINE
(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DNOV010	Urinary Cortisol

STEROID HORMONES IN SALIVA
(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV24	DHEA-S Saliva
DSNOV27	Androstenedione Saliva

PROTEIN HORMONES
(ELISAs for the determination of proteins in plasma and serum)

Prod. No.	Name
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DNOV051	Free T3
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

DIABETES MONITORING
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

CIRCULATING IMMUNO COMPLEXES
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV093	CIC-C1q
DNOV094	CIC-C3d
DNOV096	CH-50

TUMOR MARKERS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV 060	CEA
DNOV061	CA 125
DNOV062	CA 15-3
DNOV063	CA 19-9

MISCELLANEOUS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovaLisa ® Autoimmune

Autoimmune
(ELISAs for the determination of specific autoimmune antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO

Rheumatology
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
RFM3010	Rheumatoid Factor IgM

NovaLisa ® Recombinant Antigens

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HELA0220	Helicobacter pylori IgA
PHELA022	Helicobacter pylori IgA plus
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSV1G0500	Herpes simples Virus 1 (HSV 1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
MAL0620	Malaria
STRO0690	Strongyloides
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Quantitative Assays (WHO standardized)

Prod. No.	Name
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaLisa ® Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
FT41050	Free T4
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

Antigen Assays

Prod. No.	Name
NS1D4020	Dengue Virus NS1 Antigen

NovaLisa ® IgM µ-capture Assays

Prod. No.	Name
CHIM0590	Chikungunya Virus IgM µ-capture
DVM0640	Dengue Virus IgM µ-capture
RUBM0400	Rubella Virus IgM µ-capture
TOXM0460	Toxoplasma gondii IgM µ-capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Antibody Assays

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa ® Avidity Assays

Prod. No.	Name
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
AMEA7330	Avidity Measles Virus IgG
ARUB7400	Avidity Rubella Virus IgG
ATOX7460	Avidity Toxoplasma gondii IgG

NovaLisa ® Liquor Diagnostic

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

for the scope

immunodiagnostics for the determination of antibodies against Toxoplasma gondii, Rubella virus, Cytomegalovirus and Chlamydia (see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2022-05-03
Valid until	2025-05-26
Registration no.	D1055500019
Report no.	P21-01539-236808
Stuttgart	2022-05-03

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
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Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1055500019 Date 2022-05-03 Page 1 of 1

Product category	Product	Class
immunodiagnostics for the determination of antibodies against Cytomegalovirus	NovaLisa® Cytomegalovirus (CMV) IgG NovaLisa® Avidity Cytomegalovirus (CMV) IgG NovaLisa® Cytomegalovirus (CMV) IgM Cytomegalovirus (CMV) IgG Cytomegalovirus (CMV) IgM	List B, Annex II
immunodiagnostics for the determination of antibodies against Toxoplasma gondii	NovaLisa® Toxoplasma gondii IgA NovaLisa® Toxoplasma gondii IgG NovaLisa® Toxoplasma gondii IgM µ-capture NovaLisa® Avidity Toxoplasma gondii IgG Toxoplasma gondii IgA Toxoplasma gondii IgG Toxoplasma gondii IgM µ-capture Avidity Toxoplasma gondii IgG	List B, Annex II
immunodiagnostics for the determination of antibodies against Rubella virus	NovaLisa® Rubella Virus IgG NovaLisa® Avidity Rubella Virus IgG NovaLisa® Rubella Virus IgM µ-capture Rubella Virus IgG Rubella Virus IgM µ-capture	List B, Annex II
immunodiagnostics for the determination of antibodies against Chlamydia	NovaLisa® Chlamydia pneumoniae IgA NovaLisa® Chlamydia pneumoniae IgG NovaLisa® Chlamydia pneumoniae IgM NovaLisa® Chlamydia trachomatis IgA NovaLisa® Chlamydia trachomatis IgG NovaLisa® Chlamydia trachomatis IgM Novagnost Chlamydia pneumoniae IgA Novagnost Chlamydia pneumoniae IgG Novagnost Chlamydia pneumoniae IgM Novagnost Chlamydia trachomatis IgA Novagnost Chlamydia trachomatis IgG Novagnost Chlamydia trachomatis IgM Chlamydia pneumoniae IgA Chlamydia pneumoniae IgG Chlamydia pneumoniae IgM Chlamydia trachomatis IgA Chlamydia trachomatis IgG Chlamydia trachomatis IgM	List B, Annex II

Head of Certification Body

medical device certification mdc

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