MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

ENAC CERTIFICACIÓN Nº 39/C-SG055

LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

otorga el certificado número

grants the certificate no.

2013 11 0039 EN

según la norma

in accordance with the standard

UNE-EN ISO 13485:2018
(EN ISO 13485: 2016 & ISO 13485: 2016)

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios

Medical devices – Quality management systems - Requirements for regulatory purposes

a la empresa / *to the company*

Dia.Pro Diagnostic Bioprobes S.r.l.

Sede social y de fabricación/ *Headquarters and manufacturing facility*

Via G. Carducci, 27-20099-Sesto San Giovanni-Milano-Italy

Para las siguientes actividades / *For the following activities:*

Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunoquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.

Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico *in vitro*.

Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.

Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.

Modificaciones de alcance: Ver Anexo I / *see Annex I*

Fecha de validez/ *Date of validity:* **Desde/** *From:* **8-03-2019** **Hasta/***To:* **17-12-2021**

Certificación inicial/ *Initial certification date:* **27-11-2013**

Renovación / *Renewal of certification date:* **8-03-2019**

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Digitally signed by Ceaicovschi Tudor
Date: 2021.11.30 14:09:06 EET
Reason: MoldSign Signature
Location: Moldova

Fdo. Mª Jesús Lamas Díaz

13485 CERTIFICADO Revisión 17/12/2018

ENAC
CERTIFICACIÓN
Nº 39/C-SG055

ANEXO I / *ANNEX I*

CERTIFICADO UNE-EN ISO 13485:2018/ *UNE-EN ISO 13485:2018 CERTIFICATE*

Modificaciones del alcance / *Scope modifications:*

Fecha/*Date*	**Descripción de la modificación**/ *Modification description*
18-12-2018	Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico *Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques).* *Change in the level of detail of the technological scope description.*
8-03-2019	Ampliación del ámbito tecnológico para incluir: Inmunoquímica y microbiología Instrumentos y software para diagnóstico "in vitro". Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro". *Extension of technological scope:* *Immunochemistry and Microbiology* *Instruments and software for "in vitro" diagnostic* *Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic*

Madrid, 08 de marzo de 2019
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 08/03/2019
Puede comprobar la autenticidad del documento en la sede de la AEMPS: https://sede.aemps.gob.es
Localizador: L P D T J L 5 2 D F

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**CMV IgG** CODE: **CMVG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**CMV IgM** CODE: **CMVM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HP IgA** CODE: **HPA.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HP IgG** CODE: **HPG.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES S.r.l.

Rev:	05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HSV1&2 IgG** CODE: **HSVG.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HSV1&2 IgM** CODE: **HSVM.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**TOXO IgG** CODE: **TOXOG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**TOXO IgM** CODE: **TOXOM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

NOTIFIED BODY	AEMPS – n° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

Certificate Holder: **EUROIMMUN**
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

including the locations according to annex

Scope: Design, development, manufacture, installation, service and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics in humans and animals; trainings

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

Validity: The certificate is valid from 2020-05-19 until 2023-05-18.
First certification 2018

2020-05-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design, development, manufacture, installation, service and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics in humans and animals; trainings
/02	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design, development, manufacture and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software forin vitro diagnostics in humans and animals
/03	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design, development, manufacture, service and sales of immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics in humans
/04	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design, development and manufacture of immunofluorescence test systems, molecular diagnostic / genetic test systems, and test systems for the determination of infectious agents for in vitro diagnostics inhumans and animals
/05	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany	Design and development of software for in vitro diagnostics for humans

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

/06	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems and test systems for the determinationof infectious agents for in vitro diagnosticsin humans
/07	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture of immunobiochemical test Systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics for humans
/08	EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostics in humans, trainings
/09	EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	Installation, service and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics for humans and animals
/10	EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany	Manufacture of sheet metal and other components for instruments for in vitro diagnostics in humans and animals

2020-05-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

TÜVRheinland®

Certificate No.:	MD 3313978-150
Manufacturer:	**EUROIMMUN** **Medizinische Labordiagnostika AG** Seekamp 31 23560 Lübeck Germany
D-U-N-S No.:	322209263
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design, development, manufacture, installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	3313978-150
Issue Date:	2020-05-14
Effective Date:	2020-05-19
Expiry Date:	2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

D. Wiedemuth

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

TÜVRheinland®

Certificate No.: MD 3313978-150

Manufacturer: **EUROIMMUN**
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany D-U-N-S No.: 322209263	Design, development and manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics
/02	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany D-U-N-S No.: 313547785	Design and development of software for in vitro diagnostics
/03	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany D-U-N-S No.: 313547785	Design, development and manufacture of immunofluorescence test systems, molecular diagnostic / genetic test systems and, test systems for the determination of infectious agents for in vitro diagnostics

Project No.: 3313978-150

Issue Date: 2020-05-14

Effective Date: 2020-05-19

Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

D. Wiedemuth

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Certificate

TÜVRheinland®

Certificate No.: MD 3313978-150

Manufacturer: **EUROIMMUN**
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

/04	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany D-U-N-S No.: 313547786	Manufacture of immunobiochemical test systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics
/05	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany D-U-N-S No.: 342488345	Manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems and test systems for the determination of infectious agents for in vitro diagnostics
/06	EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany D-U-N-S No.: 342488344	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic

Project No.: 3313978-150
Issue Date: 2020-05-14
Effective Date: 2020-05-19
Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

D. Wiedemuth

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TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

TÜVRheinland®

Certificate No.: MD 3313978-150

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

/07	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany D-U-N-S No.: 313773638	Design, development, manufacture, service and distribution of immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics
/08	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany D-U-N-S No.: 342488342	Design, development, manufacture and sales of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics
/09	EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany D-U-N-S No.: 342488342	Manufacture of sheet metal and other components for instruments for in vitro diagnostics

Project No.: 3313978-150

Issue Date: 2020-05-14

Effective Date: 2020-05-19

Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

D. Wiedemuth

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

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TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

TÜVRheinland®

Certificate No.: MD 3313978-150

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

/10	EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany D-U-N-S No.: 322209263	Installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics

Project No.: 3313978-150
Issue Date: 2020-05-14
Effective Date: 2020-05-19
Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
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TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Scope: Design and development, manufacture, installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics

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.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

No.	Facility	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and development and manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for instruments for in vitro diagnostics
/02	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design, development, manufacture and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics
/03	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design, development, manufacture, service and distribution of immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

/04	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design, development and manufacture of immunofluorescence test systems, molecular diagnostic / genetic test systems and, test systems for the determination of infectious agents for in vitro diagnostics
/05	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany	Design and development of software for in vitro diagnostics
/06	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems and test systems for the determination of infectious agents for in vitro diagnostics
/07	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture of immunobiochemical test systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

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Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

/08	EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic
/09	EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	Installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics
/10	EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany	Manufacture of sheet metal and other components for instruments for in vitro diagnostics

Report No.: 3313978-90

Effective date: 2020-05-19

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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com
www.aptaca.com - www.vacucheck.com - www.vacuaptaca.it

P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

DECLARATION OF CONFORMITY FOR MATERIALS

Hereby we declare that Nuova Aptaca Srl In Vitro Medical Diagnostic Devices (Directive 98/79/CE) and Medical Device (93/42/CE):

1. During devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used (except for Articles of latex). The statement is formulated on the basis of information and statements provided by the producers of the raw materials used.

2. Devices are produced with materials that do not contain substances submitted to restrictions provided by 10/2001/EU Regulation and respect the global and specific migration limits in accordance with the following conditions:
   - Simulant A (distilled water) -40°C for 10 days
   - Simulant B (acetic acid solution 3% p/v) – 40°C for 10 days
   - Simulant C (Ethyl alcohol solution 10% v/v) - 40°C for 10 days
   - Simulant D1 (ethyl alcohol solution at 50% v/v) - 40°C for 10 days
   - Simulant D2 (Vegetable oil - Try substitute made with 95% ethyl alcohol as indicated by the Italian Ministerial Decree 34 of 21.03.1973) - 40°C for 10 days

   The global migration limit, together with all other specific restrictions which monomers and/or additives present in the material can be exposed to, are respected in the use conditions here above. Notes and/or simulant used for migration tests allow to fix the food or the group of food, admitted to the contact with food.
   The statement is formulated on the basis of analytical tests made by our qualified Laboratory and information and statements provided by the producers of the raw materials used

3. Devices are produced with materials that satisfy the follow requirements:
   - Directive (UE) 2015/863 (substances use restriction – phthalates, sulphates) and following updates and changes
   - 1272/2008 Regulation (labeling and use of dangerous substances) and following updates and changes
   - 10/2011 Regulation (specific migration limits) and following updates and changes 1895/2005/CE Rule (substances use restriction for food contact) and following updates and changes
   - 2011/65/UE Directive (heavy metals, RoHS) and following updating and changes
   - 1895/2005/UE Regulation (objects intended to come in contact with food) and following updates and changes

   The use in an industrial or commercial venue of the material indicated in this statement does not exclude the determination of its compliance with applicable rules of competence as well as the technological suitability for the purpose which it is intended by the user.

Canelli, lì 21 May 2019

Buono Duilio
Quality and Regulatory Affairs Manager

NUOVA APTACA s.r.l.
Regione Monforte, 30 - 14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com
www.aptaca.com - www.vacucheck.com - www.vacuaptaca.it
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

DICHIARAZIONE DI CONFORMITA' DEI MATERIALI

Con la presente si dichiara che i Dispositivi Medico Diagnostici in Vitro (Direttiva 98/79/CE e s.m.i.) e i Dispositivi Medici (93/42/CE e s.m.i.) della Nuova Aptaca Srl:

1. sono stati prodotti utilizzando materiali che non contengono gomma naturale, latex, gomme sintetiche che contengono gomme naturali (ad esclusione degli articoli in lattice). L'affermazione è formulata sulla base delle informazioni e dichiarazioni fornite dai produttori delle materie prime utilizzate.

2. sono realizzati con materiali che non contengono sostanze sottoposte a restrizioni secondo il Regolamento 10/2011 (limiti di migrazione) e s.m.i. e rispettano i limiti di migrazione globale e specifica (ove applicabile) alle seguenti condizioni:
   - simulante **A** (acqua distillata) - 40°C per 10 giorni
   - simulante **B** (soluzione di acido acetico al 3% p/v) - 40°C per 10 giorni
   - simulante **C** (soluzione di alcool etilico al 10% v/v) - 40°C per 10 giorni
   - simulante **D1** (soluzione di alcool etilico al 50% v/v) - 40°C per 10 giorni
   - simulante **D2** (Olio vegetale - Prova sostitutiva effettuata con alcool etilico al 95% secondo quanto indicato dal DM 34 del 21.03.1973) - 40°C per 10 giorni

   Il limite di migrazione globale, unitamente alle altre restrizioni specifiche alle quali possono essere sottoposti i monomeri e/o gli additivi presenti nel materiale, sono rispettati nelle condizioni d'uso sopra menzionate. Le note e/o i simulanti impiegati per le prove di migrazione consentono di determinare il prodotto alimentare o il gruppo di prodotti alimentari, ammessi al contatto con alimenti.
   L'affermazione è supportata da prove analitiche da noi condotte presso Laboratori qualificati in accordo con il Regolamento citato e sulla base delle informazioni e dichiarazioni fornite dai produttori delle materie prime utilizzate.

3. sono realizzati con materiali che soddisfano i seguenti dettati legislativi:
   - Direttiva Delegata (UE) 2015/863 (restrizione d'uso sostanze - ftalati, sulfati,) e s.m.i.
   - Regolamento 1272/2008 (etichettatura e uso sostanze pericolose) e s.m.i.
   - Direttiva 2011/65/UE (metalli pesanti, RoHS) e s.m.i.
   - Regolamento 1895/2005/CE (restrizione d'uso sostanze per contatto con alimenti) e s.m.i.
   - Regolamento 10/2011 (limiti di migrazione) e s.m.i.

   L'utilizzazione in sede industriale o commerciale del materiale indicato nella presente dichiarazione non esclude l'accertamento della sua conformità alle norme vigenti di competenza nonché della idoneità tecnologica allo scopo cui è destinato da parte dell'utilizzatore.

Canelli, lì 21.05.2019

Buono Duilio
Quality and Regulatory Manager

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

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

REGISTRATION NO. 04720Q10000336

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Chengwu Medical Products Factory

Registered Address: Southern End of Quancheng Road,Chengwu County,274200 Heze City,Shandong Province,P.R.China

Manufacturing Address: Southern End of Quancheng Road,Chengwu County

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The development,production and service of disposable virus specimen collection tube.

Date of issue: July 13,2020

Date of expiry: July 12,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

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.

ICIM

CERTIFICATO n.
CERTIFICATE No. **4265/4/C**

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

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

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*

EA: 29

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.

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.

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	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

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

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

FEDERAZIONE 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.

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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

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ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4/C**

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KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

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

UNI EN ISO 9001:2015

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

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.

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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.
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