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.

Digitally signed by Ceaicovschi Tudor
Date: 2023.03.23 15:46:30 EET
Reason: MoldSign Signature
Location: Moldova

Rev:	05/2018

Dr. Fooke-Achterrath Laboratorien GmbH, Habichtweg 16, D-41468 Neuss

Habichtweg 16 41468 Neuss
Postfach 210264 41428 Neuss
+49(0)2131 - 2984 - 0
+49(0)2131 - 2984 - 184
information@fooke-labs.de
www.fooke-labs.de

EG-Konformitäts-Erklärung

im Sinne der Richtlinie 98/79/EG über In-vitro-Diagnostika

Product Name: **Quantitative Reference System with 6 Standards**

Product Number: **076000PQ**

The declaration of conformity is valid for the kit and the components included in the kit.

Produkt-Name		Produkt-Nummer
Quantitative Reference System with 6 Standards		**076000PQ**
Anti-IgE Reference discs	CALDISC	760007
Calibrator (0,35 IU/mL)	CAL	760001
Calibrator (0,7 IU/mL)	CAL	760002
Calibrator (3,5 IU/mL)	CAL	760003
Calibrator (17,5 IU/mL)	CAL	760004
Calibrator (50 IU/mL)	CAL	760005
Calibrator (100 IU/mL)	CAL	760006

The kit and its components were designed and manufactured for the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices in the sole responsibility of:

DR. FOOKE-ACHTERRATH Laboratorien GmbH
Habichtweg 16
D-41468 Neuss
Germany

The kit and its components meet all applicable requirements of Directive 98/79/EC.
The conformity assessment procedure followed Directive 98/79/EC Annex III.

This declaration is valid until 25th May 2027.

Neuss, 18th May 2022

DR. FOOKE-ACHTERRATH Laboratorien GmbH

Dr. Margrit Fooke-Achterrath
- General Manager -

Dr. Fooke-Achterrath Laboratorien GmbH, Habichtweg 16, D-41468 Neuss

Habichtweg 16 41468 Neuss
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www.fooke-labs.de

EC-Declaration of Conformity

For the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices

Product Name: **Specific IgE EAST – Conjugat Kit**

Product Number: **0560200PKL, 0561000PKL**

The declaration of conformity is valid for the kit and the components included in the kit.

Product Name		Product Number	
Specific IgE EAST – Conjugat Kit		**0560200PKL**	**0561000PKL**
Anti IgE Enzyme-Conjugate	CONJ AP E	560202	561002
Concentrated Washing Buffer (50x)	WASHBUF C 50x	560201	561001
Substrate Buffer	SUBBUF	560203	561003
Stop Solution (1 N NaOH)	STOP NAOH	560204	561004

The kit and its components were designed and manufactured for the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices in the sole responsibility of:

DR. FOOKE-ACHTERRATH Laboratorien GmbH
Habichtweg 16
D-41468 Neuss
Germany

The kit and its components meet all applicable requirements of Directive 98/79/EC.
The conformity assessment procedure followed Directive 98/79/EC Annex III.

This declaration is valid until 25th May 2027.

Neuss, 18th May 2022

DR. FOOKE-ACHTERRATH Laboratorien GmbH

Dr. Margrit Fooke-Achterrath
- General Manager -

Certificate

mdc medical device certification GmbH
certifies that

Dr. Fooke-Achterrath Laboratorien GmbH
Habichtweg 16
41468 Neuss
Germany

for the scope

development, manufacturing and distribution of in vitro diagnostics for allergy and auto immune diagnosis as well as in vitro diagnostics for the determination of parameters in the infection serology

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2022-07-28
Valid until	2025-07-27
Registration no.	D1060800022
Report no.	P22-00403-230765
Stuttgart	2022-07-28

Head of Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10462 rev. 7

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS

Zone Industrielle

61500 SEES FRANCE

pour les activités

for the activities

Conception, production, contrôle et commercialisation de produits de chimie cliniques pour le diagnostic in vitro. Validation de la combinaison réactifs et automates. Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.

Design, production, control and sales of clinical chemistry products intended to be used for in vitro diagnostics. Validation of the combination reagents and analyzers. Distribution of clinical chemistry analyzers and products for in vitro diagnostics.

réalisées sur le(s) site(s) de

performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / *Effective date :* **July 28th, 2020 (included)**

Valable jusqu'au / *Expiry date :* **July 27th, 2023 (included)**

Etabli le / *Issued on :* **July 17th, 2020**

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Lionel DREUX
Certification Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

GMED N° 10462–7
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 10462-6

ISO 9001 -NF EN ISO 13485

ELITechGroup SEPPIM
REAGENTS

Zone Industrielle – 61500 SEES – France
Tél. : + 33 (0)2 33 81 21 00 / Fax : + 33 (0)2 33 28 77 51

DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les dispositifs appartenant au groupe 5 «CONTRÔLES/ CALIBRANTS/ STANDARDS », référencés dans la liste ci-jointe, sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.
Cette déclaration s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the devices belonging to Group 5, "CONTROLS/ CALIBRATORS/ STANDARDS", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to *in vitro* diagnostic medical devices and to the public health code.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los dispositivos pertenecientes al grupo 5 : "CONTROLES/ CALIBRADORES/ ESTÁNDARES", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico *in vitro* y el código de salud pública.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

SEPPIM S.A.S
4 rue Auguste Mottin
Zone Industrielle
61500 SEES – FRANCE
Tél. +33 (0)2 33 81 21 00 - Fax +33 (0)2 33 28 77 51
SIRET : 318 365 228 00036

Françoise DEBIAIS,
Président
President
Presidente

Société par actions simplifiée au Capital de 1 219 592.14 €
SIRET 318 365 228 00036 APE 2059Z
RC ALENCON 318 365 228

ISO 9001 -NF EN ISO 13485

ELITechGroup SEPPIM REAGENTS

Zone Industrielle – 61500 SEES – France
Tél. : + 33 (0)2 33 81 21 00 / Fax : + 33 (0)2 33 28 77 51

GROUPE 5 – CONTROLES/CALIBRANTS/STANDARDS
GROUP 5 – CONTROLS/CALIBRATORS/STANDARDS
GRUPO 5 – CONTROLES/CALIBRADORES/ESTÁNDARES

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
CK-MB CONTROL	CKMB-0900	DOS-CE-CKMB-CT
ELICAL 2	CALI-0550	DOS-CE-CALI2
ELITROL I	CONT-0060	DOS-CE-ELIT I
ELITROL II	CONT-0160	DOS-CE-ELIT II
ISE CONTROL I	ISCT-0046	DOS-CE-ISCT
ISE CONTROL II	ISCT-0047	
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	DOS-CE-HDLL-CAL
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	DOS-CE-LDLL-CAL
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	DOS-CE-CHOL200
CREATININE Standard 2 mg/dL	CREN-0055	DOS-CE-CREN2
GLUCOSE Standard 100 mg/dL	GLUP-0055	DOS-CE-GLUP100
MICROPROTEIN Standard 20 mg/dL	PRTP-0020	DOS-CE-PRTP20
MICROPROTEIN Standard 100 mg/dL	PRTP-0022	DOS-CE-PRTP100
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	DOS-CE-PRTU100
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	DOS-CE-TRIG200
UREA Standard 50 mg/dL	URUV-0055	DOS-CE-URUV50
URIC ACID Standard 6 mg/dL	ACUR-0055	DOS-CE-ACUR6

VG

SEPPIM S.A.S
4 rue Auguste Mottin
Zone Industrielle
61500 SEES FRANCE
Tél. +33 (0)2 33 81 21 00 - Fax +33 (0)2 33 28 77 51
SIRET : 318 365 228 00036

Société par actions simplifiée au Capital de 1 219 592.14 €
SIRET 318 365 228 00036 APE 2059Z
RC ALENCON 318 365 228

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

UKAS MANAGEMENT SYSTEMS
001

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products:
- Immuno-biochemical test systems
- Immunofluorescence test systems
- Molecular diagnostic test systems
- Test systems for the determination of pathogens

Replaces Certificate, Registration No.: HL 60139384 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products included:

Anti-CMV ELISA (IgG, IgM, Avidity IgG, CSF IgG, p52 IgM)
Anti-Chlamydia ELISA (IgA, IgG, IgM)
Anti-Chlamydia trachomatis ELISA (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae ELISA (IgA, IgG, IgM)
Anti-Toxoplasma gondii ELISA (IgG, IgM, Avidity IgG, CSF IgG, IgA)
Anti-Rubella Virus ELISA (IgG, Avidity IgG, CSF IgG, Glycoprotein IgM)

Anti-Toxoplasma gondii IIFT (IgG, IgM)
Anti-Toxoplasma gondii IIFT EUROPattern (IgG, IgM)

Anti-Chlamydia MIF (IgA, IgG, IgM)
Anti-Chlamydia trachomatis MIF (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae MIF (IgA, IgG, IgM)
Anti-Chlamydia MIF EUROPattern (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae MIF EUROPattern (IgA, IgG, IgM)

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products included:

Anti-Rubella Virus WESTERNBLOT (IgG)
Anti-Chlamydia HP EUROLINE-WB (IgA, IgG)

Multimarker Controls for Euroimmun ELISA

EUROLINE Anti-TO.R.C.H. Profile (IgG, IgM)
EUROLINE Anti-TO.R.C.H. 10-Profile (IgG)
EUROLINE Anti-CMV (IgG, IgM)

EUROArray STI

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
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EC Certificate

TÜVRheinland®

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and Development, Manufacture
/02	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design and Development, Manufacture
/03	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

No.	Location	Scope
/04	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design and Development, Manufacture, final Quality Control
/05	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Manufacture
/06	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

Certificate No.:	MD 1102316-60
Manufacturer:	**EUROIMMUN** **Medizinische Labordiagnostika AG** Seekamp 31 23560 Lübeck Germany
REPs Facility ID:	F001097
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance 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.:	3350288-160
Issue Date:	2021-11-30
Effective Date:	2021-11-30
Expiry Date:	2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M. Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087979?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1102316-60

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following sites:

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany REPs Facility ID: F001097	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, including manufacture of sheet metal and other components for instruments for in vitro diagnostics
/02	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany REPs Facility ID: F001097	Design and development of software for in vitro diagnostics
/03	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany REPs Facility ID: F001097	Design, development and manufacture of immunofluorescence test systems for in vitro diagnostics

Project No.: 3350288-160

Issue Date: 2021-11-30

Effective Date: 2021-11-30

Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M. Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

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TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1102316-60

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following sites:

/04	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany REPs Facility ID: F002021	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 REPs Facility ID: F002019	Manufacture of immunobiochemical test systems and immunofluorescence test systems for in vitro diagnostics
/06	EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany REPs Facility ID: F002018	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic

Project No.: 3350288-160

Issue Date: 2021-11-30

Effective Date: 2021-11-30

Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M. Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

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TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1102316-60

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following sites:

/07	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany REPs Facility ID: F002017	Design, development, manufacture, service and distribution of immunobiochemical test systems, immunofluorescence test systems and instruments / software for in vitro diagnostics
/08	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany REPs Facility ID: F002020	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, including manufacture of sheet metal and other components for instruments for in vitro diagnostics
/09	EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany REPs Facility ID: F002020	Manufacture of sheet metal and other components for instruments for in vitro diagnostics

Project No.: 3350288-160

Issue Date: 2021-11-30

Effective Date: 2021-11-30

Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M. Sc. Irene Carraretto
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Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1102316-60

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG

Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following sites:

/10	EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany REPs Facility ID: F001097	Design, development, 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.: 3350288-160

Issue Date: 2021-11-30

Effective Date: 2021-11-30

Expiry Date: 2023-05-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M. Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087979?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, 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
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

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 Zertifizierungsstelle

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

/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

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

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

Expiry date: 2023-05-18

Issue date: 2020-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

D. Wiedemuth

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

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

2021-10-12 (Change)

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	c/o 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	c/o 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 for in vitro diagnostics in humans and animals
/03	c/o EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design, development, manufacture, service and sales of immunobiochemical test systems, immunofluorescence test systems and instruments / software for in vitro diagnostics for humans
/04	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design, development and manufacture of immunofluorescence test systems for in vitro diagnostics for humans and animals
/05	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany	Design and development of software for in vitro diagnostics for humans and animals

Annex to certificate

Standard **ISO 9001:2015**

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

/06	c/o EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture of immunobiochemical test systems and immunofluorescence test systems for in vitro diagnostics for humans
/07	c/o 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	c/o 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	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	Design, development, 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; trainings
/10	c/o 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

2021-10-12

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14
Expiry Date: 2024-04-13

...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Effective Date: 2021-04-14

Latest Revision Date: 2021-04-13

Expiry Date: 2024-04-13

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0229DC DOI 2015/08 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5392	Thrombin Time	55987

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0511 DC DOI 2013/08 (3)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 05 Aug 2013

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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-DC-0814 Rev. 1

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5560	APTT Si L Minus	55981

I, the undersigned, declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 24 Nov 2020

Helena Biosciences Europe,
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