MINISTERIO DE SANIDAD

CNCPS CENTRO NACIONAL DE CERTIFICACIÓN DE PRODUCTOS SANITARIOS

EL CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS

THE CENTRO NACIONAL DE CERTIFICACION DE 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.

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 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 and manufacturing of instruments and software for "in vitro" diagnostic.

Fecha de validez / *Date of validity:* **Desde/** *From:* **18-11-2023** **Hasta/** *To:* **17-11-2026**

Renovación / *Renewal of certification date:* **18-11-2023**

Digitally signed by Ce[illegible]
Date: 2025.03.12 11:51:05 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

ENAC CERTIFICACIÓN ISO 17021 Nº39 / C-SG055

Madrid, 17 de noviembre de 2023
Jefa del Centro Nacional de Certificación de Productos Sanitarios

Fdo. Gloria Hernández Hernández

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Fecha de la firma: 17/11/2023
Puede comprobar la autenticidad del documento en la sede de la AEMPS:https://localizador.aemps.es

CSV: N F 9 Q K D G 9 E A

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secretariaCNCps@certificaps.gob.es

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Tel.: (+34) 91 822 5130

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE
EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2003 12 0388 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To***	**26-05-2025**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.**
Dirección/*Address*: **Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)**
Representante autorizado ante la UE/*Authorized EU representative*: Idem

Para el producto/*For the product*:

Categoría/*Category*: **Productos sanitarios para diagnóstico "in vitro"**/ *In vitro diagnostic medical devices*
Grupo genérico/ *Generic group*: **Diagnóstico de enfermedades infecciosas** / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en el Anexo de este Certificado/*Specified in Annex to this Certificate*

Elaborado en/*In the facilities*:

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

Fecha inicial/ *Initial date:* 11/12/2003
Fecha de prórroga anterior/ *Previous extension date:* 26/11/2018

Este certificado debe ir acompañado por certificado de examen de diseño: SI / *This certificate must be accompanied by design examination certificate*: *YES*

Este certificado es consecuencia de la auditoria del sistema completo de garantía de calidad y del examen de la documentación técnica contenida en el expediente nº 2003 05 0240, y garantiza que los productos descritos cumplen los requisitos de la Directiva./ *This certificate is issued on the full quality assurance system audit, and the examination of the technical documentation contained in dossier nº 2003 05 0240, and guarantees that the described products fulfils the requirements of the Directive.*

Madrid, 19 de mayo de 2022
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 (AEMPS)
Fecha de la firma: 19/05/2022
Puede comprobar la autenticidad del documento en la sede de la AEMPS:https://localizador.aemps.es
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ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2003 12 0388 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.**
Dirección/*Address*: **Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)**
Representante autorizado ante la UE/*Authorized EU representative*: **Idem**

Tipo de producto/ *Devices type*: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas humanas./ *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/ *Classification:* Lista A del Anexo II / *List A of Annex II*

1. **Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de Inmunoabsorción enzimática (ELISA)/** *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0201; IVD 0202; IVD 0203]**

1.1. HBs Ab

- SAB.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2003 12 0390 ED

1.2. HBc Ab

- BCAB.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2003 12 0391 ED

1.3. HBc IgM

- BCM.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2004 03 0424 ED

1.4. HBe Ag & Ab

- HBE.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2004 03 0425 ED

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1.5. HBs Ag Confirmation

- SCONF.CE (20 tests)
- SCONF.CE.40 (40 tests)

Descrito en el certificado/ *Described in the certificate* 2006 11 0511 ED

1.6. HBs Ag one Version ULTRA

- SAG1ULTRA.CE (192 tests)
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2008 12 0588 ED

1.7. HCV Ab

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0392 ED

1.8. HCV Ab Confirmation

- CCONF.CE (12 tests)

Descrito en el certificado/ *Described in the certificate* 2005 09 0485 ED

1.9. HCV IgM

- CVM.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2007 09 0532 ED

1.10. HCV Ab (Format 20)

- CVAB.CE.EG (192 tests)
- CVAB.CE.EG.96 (96 tests)
- CVAB.CE.EG.480 (480 tests)
- CVAB.CE.EG.960 (960 tests)

Descrito en el certificado/ *Described in the certificate* 2015 10 0842 ED

1.11. HDV Ab

- DAB.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0393 ED

1.12. HDV Ag

- DAG.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0394 ED

1.13. HDV IgM

- DIM.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0395 ED

1.14. HTLV I & II Ab Version ULTRA

- HTLVABULTRA.CE (192 tests)
- HTLVABULTRA.CE.96 (96 tests)
- HTLVABULTRA.CE.480 (480 tests)
- HTLVABULTRA.CE.960 (960 tests)
- HTLVABULTRA.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2011 11 0775 ED

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1.15. HIV Ab & Ag

- IVCOMB.CE (192 tests)
- IVCOMB.CE.96 (96 tests)
- IVCOMB.CE.480 (480 tests)
- IVCOMB.CE.960 (960 tests)
- IVCOMB.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2008 02 0539 ED

2. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de PCR en tiempo real/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Real-Time PCR* **[NANDO: IVD 0203]**

2.1 HBV DNA Quantitation (QT)

- HBVDNAQT.CE (50 tests)
- HBVDNAQT.CE.25 (25 tests)
- HBVDNAQT.CE.100 (100 tests)
- HBVDNAQT.CE.150 (150 tests)

Descrito en el certificado/ *Described in the certificate* 2012 09 0790 ED

2.2 HDV RNA Quantitation (QT)

- DRNA.CE (50 tests)
- DRNA.CE.25 (25 tests)
- DRNA.CE.100 (100 tests)
- DRNA.CE.150 (150 tests)

Descrito en el certificado/ *Described in the certificate* 2009 11 0660 ED

2.3 HDV ONESTEP Quantitation (QT)

- HDVONEQT.CE (50 tests)
- HDVONEQT.CE.25 (25 tests)
- HDVONEQT.CE.100 (100 tests)

Descrito en el certificado/ *Described in the certificate* 2022 04 0973 ED

3 Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante ensayos de quimioluminiscencia (CLIA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Chemiluminescence Immunoassay (CLIA)* **[NANDO: IVD 0201; IVD 0202; IVD 0203]**

3.1 DIA.CHEMILUX HCV Ab

- RACVAB.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2015 01 0834 ED

3.2 DIA.CHEMILUX HBs Ag

- RASAG.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2015 10 0841 ED

3.3 DIA.CHEMILUX HIV Ab & Ag

- RAIVCOMB.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2016 02 0844 ED

3.4 DIA.CHEMILUX HBc Ab

- RABCAB.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2017 07 0863 ED

ANEXO Nº/*ANNEX NO:* I

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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2003 12 0388 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

3.5 DIA.CHEMILUX HTLV I & II Ab

- RAHTLVAB.CE (100 tests)	Descrito en el certificado/ *Described in the certificate* 2018 11 0878 ED

3.6 DIA.CHEMILUX HDV Ab

- RADAB.CE (100 tests)	Descrito en el certificado/ *Described in the certificate* 2020 07 0932 ED

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity*.

Madrid, 19 de mayo de 2022
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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ORGANISMO NOTIFICADO 0318

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2004 05 0442 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To***	**26-05-2025**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.**
Dirección/*Address*: **Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)**
Representante autorizado ante la UE/*Authorized EU representative*: Idem

Para el producto/*For the product*:

Categoría/*Category*: **Productos sanitarios para diagnóstico "in vitro"**/ *In vitro diagnostic medical devices*
Grupo genérico/ *Generic group*: **Diagnóstico de enfermedades infecciosas** / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en el Anexo de este Certificado/*Specified in Annex to this Certificate*

Elaborado en/*In the facilities*:

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

Fecha inicial/ *Initial date:* 10/05/2014
Fecha de prórroga anterior/ *Previous extension date:* 26/11/2018

Este certificado debe ir acompañado por certificado de examen de diseño: NO / *This certificate must be accompanied by design examination certificate*: *NO*

Este certificado es consecuencia de la auditoria del sistema completo de garantía de calidad y del examen de la documentación técnica contenida en el expediente nº 2003 05 0240, y garantiza que los productos descritos cumplen los requisitos de la Directiva./ *This certificate is issued on the full quality assurance system audit, and the examination of the technical documentation contained in dossier nº 2003 05 0240, and guarantees that the described products fulfils the requirements of the Directive.*

Madrid, 19 de mayo de 2022
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 (AEMPS)
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ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX NO:* I

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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2004 05 0442 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.**
Dirección/*Address*: **Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)**
Representante autorizado ante la UE/*Authorized EU representative*: **Idem**

Tipo de producto/ *Devices type*: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas humanas. / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/ *Classification:* Lista B del Anexo II / *List B of Annex II*

1. **Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de Inmunoabsorción enzimática (ELISA)/** *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0303; IVD 0305]**

1.1. CMV IgM

- CMV.CE (96 tests)

1.2. CMV IgG

- CMVG.CE (96 tests)

1.3. Toxo IgM

- TOXOM.CE (96 tests)

1.4. Toxo IgG

- TOXOG.CE (96 tests)

1.5. RUB IgM

- RUBM.CE (96 tests)

1.6. RUB IgG

- RUBG.CE (96 tests)
- RUBG.CE.192 (192 tests)
- RUBG.CE.480 (480 tests)

1.7. TORCH IgM

- TORCHM.CE (96 tests)

1.8. *Chlamydia Trachomatis* IgG

- CTG.CE (96 tests)

-

1.9. *Chlamydia Trachomatis* IgM

- CTM.CE (96 tests)

1.10. *Chlamydia Trachomatis* IgA

- CTA.CE (96 tests)

1.11. *Chlamydia Pneumoniae* IgG

- CPG.CE (96 tests)

1.12. *Chlamydia Pneumoniae* IgM

- CPM.CE (96 tests)

1.13. *Chlamydia Pneumoniae* IgA

- CPA.CE (96 tests)

2. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de PCR en tiempo real/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Real-Time PCR* [NANDO: IVD 0303; IVD 0305]

2.1. CMV DNA Quantitation (QT) 2nd Generation

- CMVDNAQT.2G. CE (50 tests)
- CMVDNAQT.2G.CE.25 (25 tests)
- CMVDNAQT.2G.CE.100 (100 tests)
- CMVDNAQT.2G.CE.150 (150 tests)

-

2.2. Dx CMV Assay

- 37020 (96 tests)

2.3. *Toxoplasma Gondii* DNA

- TOXODNA.CE (50 tests)
- TOXODNA.CE.25 (25 tests)
- TOXODNA.CE.100 (100 tests)
- TOXODNA.CE.150 (150 tests)

2.4. *Chlamydia Trachomatis* DNA

- CTDNA.CE (50 tests)
- CTDNA.CE.25 (25 tests)
- CTDNA.CE.100 (100 tests)
- CTDNA.CE.150 (150 tests)

2.5. PRIME MDx CMV DNA Quantitative detection kit

- 56449 (24 tests)
- 56450 (48 tests)

2.6. PRIME MDx *Toxoplasma gondii* DNA detection kit

- 5647 (24 tests)
- 5648 (48 tests)

3. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante ensayos de quimioluminiscencia (CLIA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Chemiluminescence Immunoassay (CLIA)* **[NANDO: IVD 0303; IVD 0305]**

3.1 DIA.CHEMILUX Cytomegalovirus IgM

- RACMVM.CE (100 tests)

3.2 DIA.CHEMILUX Cytomegalovirus IgG

- RACMVG.CE (100 tests)

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3.3 DIA.CHEMILUX Toxoplasma IgM

- RATOXOM.CE (100 tests)

3.4 DIA.CHEMILUX Toxoplasma IgG

- RATOXOG.CE (100 tests)

3.5 DIA.CHEMILUX Rubella IgM
- RARUBM.CE (100 tests)

3.6 DIA.CHEMILUX Rubella IgG
- RARUBG.CE (100 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de mayo de 2022
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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 and development, manufacture, installation, service and sales of immuno-biochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for vitro diagnostics, for 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 2023-05-19 until 2026-05-18.
First certification 2018

2023-05-17

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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

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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 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 for humans and animals; trainings
/02	c/o EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design and 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 for humans and animals
/03	c/o EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design and 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 and development and manufacture of immunofluorescence test systems for in vitro diagnostics for humans and animals

Annex to certificate

Standard **ISO 9001:2015**

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

/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
/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 for humans; trainings
/09	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	Design and 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

Annex to certificate

Standard **ISO 9001:2015**

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

/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 for humans and animals
/11	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Berzdorfer See 7 02829 Markersdorf Germany	Warehousing of immunobiochemical test systems and instruments for in vitro diagnostics for humans

2023-05-17

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HX 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

EUDAMED Single Registration No.: DE-MF-000005296

Products: Products of class B:

IMMUNOCHEMISTRY (IMMUNOLOGY)

IVR 0602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
W01021090 - VARIOUS AUTO-IMMUNE DISEASE

IVR 0603: Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances
W01020299 - ALLERGY TESTS - OTHER
W01020201 - IMMUNOGLOBULIN E - TOTAL

IVR 0608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01020702 - VITAMINES

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market. If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market. If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.10 is required before placing them on the market.

Report No.: 1090492-40

Effective date: 2023-05-10

Expiry date: 2028-05-09

Issue date: 2023-05-10

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-IVDR-097

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HX 1483000-1

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

INFECTIOUS DISEASES

IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W01050808 - CONTROLS - INFECT. IMMUNOLOGY
W01050404 - EPSTEIN BARR VIRUS
W01050502 - MISCELLANEOUS PARASITOLOGY
W01050117 - OTHER BACTERIOLOGY IMMUNOASSAYS
W01050406 - OTHER VIROLOGY ANTIGEN/ANTIBODY DETECTION

IVR 0504: Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging
W01050117 - OTHER BACTERIOLOGY IMMUNOASSAYS

CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS

IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W0201020192 - AUTOMATED IMMUNOCHEMISTRY ANALYSERS – IVD MEDICAL DEVICE SOFTWARE

Products of class C

IMMUNOCHEMISTRY (IMMUNOLOGY)

IVR 0602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
W01021090 - VARIOUS AUTO-IMMUNE DISEASE

Report No.: 1090492-40

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EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices,
Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HX 1483000-1

Manufacturer:

EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

INFECTIOUS DISEASES

IVR 0501: Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents
W01050501 - TOXOPLASMA

IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W01050403 - HERPES SIMPLEX VIRUS
W01050405 - OTHER VIROLOGY - NA REAGENTS
W01050705 - MULTIPLE PANELS FOR INFECTIONS - VARIOUS
W01050107 - MYCOBACTERIA GENUS + SPECIES

GENETIC TESTING

IVR 0402: Devices intended to be used to predict genetic disease/disorder risk and prognosis
W01060101 - MONOGENETIC DISORDERS

NUCLEIC ACID TESTING INSTRUMENTS

IVR 0402: Devices intended to be used to predict genetic disease/disorder risk and prognosis
W02050292 - MICRO-ARRAY INSTRUMENTS – IVD MEDICAL DEVICE SOFTWARE

CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS

IVR 0501: Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents
W0201020192 - AUTOMATED IMMUNOCHEMISTRY ANALYSERS – IVD MEDICAL DEVICE SOFTWARE

Report No.: 1090492-40

Effective date: 2023-05-10

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

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

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EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HX 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial issuing	2023-05-10

Report No.: 1090492-40

Effective date: 2023-05-10

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

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 REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices with the identification number 0197.

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
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Seramun Diagnostica GmbH	**EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY** *Serazym®* Adenovirus

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Deutschland, erklärt in eigener Verantwortung gemäß der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitäts-bewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewandt wurde:

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices, that the following products fulfill the basic requirements according to Annex I of Directive 98/79/EC and that the conformity assessment procedure according to Annex III of Directive 98/79/EC has been applied:

Angewandte harmonisierte Normen /	**EN ISO 13485:2016**
Applied harmonized norms:	**EN ISO 14971:2019**
	EN ISO 18113-1:2011
	EN ISO 18113-2:2011
	EN ISO 15223-1:2021

Produktgruppe / Product Group:

Gastrointestinale Infektionskrankheiten / Gastrointestinal Infectious Diseases		
Produkt-Bezeichnung / Product Name	**Artikel-Nummer / Order Number**	**EDMS-Code / EDMS Code**
Serazym® Adenovirus	E-017 E-017-A2	15-04-80-01-00

Heidesee, 2022-04-08

Seramun Diagnostica GmbH
Spreenhagener Str. 1 • 15754 Heidesee
info@seramun.com • T +49 33767 791-10

Peter Lobeda

Geschäftsführung /
Managing Director

Michaela Briesenick

Stellv. Abteilungsleitung Regulatory Affairs /
Deputy Director of Regulatory Affairs

Eine Überarbeitung der Konformitätserklärung erfolgt bei Änderung und/oder Ergänzung von Produkten. /
A revision of the declaration of conformity will take place with change and/or addition of products.

Seramun Diagnostica GmbH	**EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY** *Serazym*® Rotavirus

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Deutschland, erklärt in eigener Verantwortung gemäß der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitäts-bewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewandt wurde:

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices, that the following products fulfill the basic requirements according to Annex I of Directive 98/79/EC and that the conformity assessment procedure according to Annex III of Directive 98/79/EC has been applied:

Angewandte harmonisierte Normen /	**EN ISO 13485:2016**
Applied harmonized norms:	**EN ISO 14971:2019**
	EN ISO 18113-1:2011
	EN ISO 18113-2:2011
	EN ISO 15223-1:2021

Produktgruppe / Product Group:

Gastrointestinale Infektionskrankheiten / Gastrointestinal Infectious Diseases		
Produkt-Bezeichnung / Product Name	**Artikel-Nummer / Order Number**	**EDMS-Code / EDMS Code**
Serazym® Rotavirus	E-020 E-020-A2	15-04-80-06-00

Heidesee, 2022-04-08

Seramun Diagnostica GmbH
Spreenhagener Str. 1 • 15754 Heidesee
info@seramun.com • T +49 33767 791-10

Peter Lobeda

Geschäftsführung /
Managing Director

Michaela Briesenick

Stellv. Abteilungsleitung Regulatory Affairs /
Deputy Director of Regulatory Affairs

Eine Überarbeitung der Konformitätserklärung erfolgt bei Änderung und/oder Ergänzung von Produkten. /
A revision of the declaration of conformity will take place with change and/or addition of products.

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, GERMANY

Tel.: +49-33767-791 10, Fax: +49-33767-791 99, E-Mail: info@seramun.com, Homepage: www.seramun.com

EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY

Serazym® Clostridium difficile Toxin A+B

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Deutschland, erklärt in eigener Verantwortung gemäß der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitäts-bewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewandt wurde:

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices, that the following products fulfill the basic requirements according to Annex I of Directive 98/79/EC and that the conformity assessment procedure according to Annex III of Directive 98/79/EC has been applied:

Angewandte harmonisierte Normen /	**EN ISO 13485:2016**
Applied harmonized norms:	**EN ISO 14971:2019**
	EN ISO 18113-1:2011
	EN ISO 18113-2:2011
	EN ISO 15223-1:2021

Produktgruppe / Product Group:

Gastrointestinale Infektionskrankheiten / Gastrointestinal Infectious Diseases		
Produkt-Bezeichnung / Product Name	**Artikel-Nummer / Order Number**	**EDMS-Code / EDMS Code**
Serazym® Clostridium difficile Toxin A+B	E-040 E-040-A2	15-01-90-02-00

Heidesee, 2022-04-08

Seramun Diagnostica GmbH
Spreenhagener Str. 1 • 15754 Heidesee
info@seramun.com • T +49 33767 791-10

Peter Lobeda

Geschäftsführung /
Managing Director

Michaela Briesenick

Stellv. Abteilungsleitung Regulatory Affairs /
Deputy Director of Regulatory Affairs

Eine Überarbeitung der Konformitätserklärung erfolgt bei Änderung und/oder Ergänzung von Produkten. /
A revision of the declaration of conformity will take place with change and/or addition of products.

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, GERMANY

Tel.: +49-33767-791 10, Fax: +49-33767-791 99, E-Mail: info@seramun.com, Homepage: www.seramun.com

Seramun Diagnostica GmbH	**EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY** *Serazym®* Astrovirus

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Deutschland, erklärt in eigener Verantwortung gemäß der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitäts-bewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewandt wurde:

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Angewandte harmonisierte Normen /	**EN ISO 13485:2016**
Applied harmonized norms:	**EN ISO 14971:2019**
	EN ISO 18113-1:2011
	EN ISO 18113-2:2011
	EN ISO 15223-1:2021

Produktgruppe / Product Group:

Gastrointestinale Infektionskrankheiten / Gastrointestinal Infectious Diseases		
Produkt-Bezeichnung / Product Name	**Artikel-Nummer / Order Number**	**EDMS-Code / EDMS Code**
Serazym® Astrovirus	E-045 E-045-A2	15-04-80-90-00

Heidesee, 2022-04-08

Seramun Diagnostica GmbH
Spreenhagener Str. 1, 15754 Heidesee
info@seramun.com

Peter Lobeda

Geschäftsführung /
Managing Director

Michaela Briesenick

Stellv. Abteilungsleitung Regulatory Affairs /
Deputy Director of Regulatory Affairs

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A revision of the declaration of conformity will take place with change and/or addition of products.

Seramun Diagnostica GmbH	**EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY** *Serazym*® Norovirus

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Deutschland, erklärt in eigener Verantwortung gemäß der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitäts-bewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewandt wurde:

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices, that the following products fulfill the basic requirements according to Annex I of Directive 98/79/EC and that the conformity assessment procedure according to Annex III of Directive 98/79/EC has been applied:

Angewandte harmonisierte Normen /	**EN ISO 13485:2016**
Applied harmonized norms:	**EN ISO 14971:2019**
	EN ISO 18113-1:2011
	EN ISO 18113-2:2011
	EN ISO 15223-1:2021

Produktgruppe / Product Group:

Gastrointestinale Infektionskrankheiten / Gastrointestinal Infectious Diseases		
Produkt-Bezeichnung / Product Name	**Artikel-Nummer / Order Number**	**EDMS-Code / EDMS Code**
Serazym® Norovirus	E-061 E-061-A2	15-04-90-90-00

Heidesee, 2022-04-08

Seramun Diagnostica GmbH
Spreenhagener Str. 1 • 15754 Heidesee
info@seramun.com • T +49 33767 791 10

Peter Lobeda

Geschäftsführung /
Managing Director

Michaela Briesenick

Stellv. Abteilungsleitung Regulatory Affairs /
Deputy Director of Regulatory Affairs

Eine Überarbeitung der Konformitätserklärung erfolgt bei Änderung und/oder Ergänzung von Produkten. /
A revision of the declaration of conformity will take place with change and/or addition of products.

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, GERMANY

Tel.: +49-33767-791 10, Fax: +49-33767-791 99, E-Mail: info@seramun.com, Homepage: www.seramun.com

Seramun Diagnostica GmbH	**EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY** *Serazym®* Giardia

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Deutschland, erklärt in eigener Verantwortung gemäß der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitäts-bewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewandt wurde:

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices, that the following products fulfill the basic requirements according to Annex I of Directive 98/79/EC and that the conformity assessment procedure according to Annex III of Directive 98/79/EC has been applied:

Angewandte harmonisierte Normen /	**EN ISO 13485:2016**
Applied harmonized norms:	**EN ISO 14971:2019**
	EN ISO 18113-1:2011
	EN ISO 18113-2:2011
	EN ISO 15223-1:2021

Produktgruppe / Product Group:

Gastrointestinale Infektionskrankheiten / Gastrointestinal Infectious Diseases		
Produkt-Bezeichnung / Product Name	**Artikel-Nummer / Order Number**	**EDMS-Code / EDMS Code**
Serazym® Giardia	E-106 E-106-A	15-05-10-08-00

Heidesee, 2022-04-08

Seramun Diagnostica GmbH
Spreenhagener Str. 1 • 15754 Heidesee
info@seramun.com • T +49 33767 791-10

Peter Lobeda

Geschäftsführung /
Managing Director

Michaela Briesenick

Stellv. Abteilungsleitung Regulatory Affairs /
Deputy Director of Regulatory Affairs

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A revision of the declaration of conformity will take place with change and/or addition of products.

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, GERMANY

Tel.: +49-33767-791 10, Fax: +49-33767-791 99, E-Mail: info@seramun.com, Homepage: www.seramun.com

Seramun Diagnostica GmbH	**EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY** *Serazym®* Clostridium difficile GDH

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Deutschland, erklärt in eigener Verantwortung gemäß der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitäts-bewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewandt wurde:

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices, that the following products fulfill the basic requirements according to Annex I of Directive 98/79/EC and that the conformity assessment procedure according to Annex III of Directive 98/79/EC has been applied:

Angewandte harmonisierte Normen /	**EN ISO 13485:2016**
Applied harmonized norms:	**EN ISO 14971:2019**
	EN ISO 18113-1:2011
	EN ISO 18113-2:2011
	EN ISO 15223-1:2021

Produktgruppe / Product Group:

Gastrointestinale Infektionskrankheiten / Gastrointestinal Infectious Diseases		
Produkt-Bezeichnung / Product Name	**Artikel-Nummer / Order Number**	**EDMS-Code / EDMS Code**
Serazym® Clostridium difficile GDH	E-107 E-107-A2	15-01-90-02-00

Heidesee, 2022-04-08

Seramun Diagnostica GmbH
Spreenhagener Str. 1 • 15754 Heidesee
info@seramun.com • T +49 33767 791-10

Peter Lobeda

Geschäftsführung /
Managing Director

Michaela Briesenick

Stellv. Abteilungsleitung Regulatory Affairs /
Deputy Director of Regulatory Affairs

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A revision of the declaration of conformity will take place with change and/or addition of products.

Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, GERMANY

Tel.: +49-33767-791 10, Fax: +49-33767-791 99, E-Mail: info@seramun.com, Homepage: www.seramun.com

Сертификат соответствия

Настоящий сертификат удостоверяет, что организация

АО «Вектор-Бест»

Российская Федерация, 630559, Новосибирская область, р. п. Кольцово,
Научно-производственная зона, корпус 36

подтвердила соответствие Системы Менеджмента Качества требованиям

ISO 13485:2016

В отношении области деятельности, представленной ниже

Проектирование, разработка и производство медицинских изделий для диагностики in vitro (ИФА)

Номер сертификата **209535/A/0001/UK/RUS**

Сертификат с номером 0001, подтверждает, что клиент имеет одну сертифицированную площадку, которая является головным офисом или основной площадкой применительно к области, сертифицированной в URS. Сертификат с номером 0002, или более (например: xxxx/B/0002/UK/En), выдается клиенту, у которого есть более одной площадки, сертифицированной в URS, соответственно, применяется следующее заявление - "Действительность данного сертификата, зависит от действительности основного сертификата".

Начало сертификационного цикла	Номер версии	Дата окончания срока действия сертификата	Сертификационный цикл
05 октября 2022	**1**	**04 октября 2025**	**1**
Дата редакции	Номер редакции	Первоначальная дата выпуска сертификата	Номер схемы
06 октября 2022	**1**	**05 октября 2022**	**Не применяется**

Подробное описание данных выше см. на http://www.urs-holdings.com/logos-and-regulations

Выпущен *От имени менеджера по сертификации*

EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 are in conformity with relevant provisions of EC Council Directive 98/79/EC on in vitro diagnostic medical devices and fulfill the essential requirements of that directive.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2016+AC:2016 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2015 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

AO Vector-Best
Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49.

European authorized representative:

BIORON GmbH
Address: In den Rauhweiden 20, 67354 Roemerberg, Germany, tel.: +49 (0) 6232 298 450.

Date: 2020/12/09
Place: Novosibirsk

Murat Khusainov
General Director AO Vector-Best

Valid until: 2022/07/03

No.	Product name	Identification data	REF
1.	Vectohep A-IgG	Enzyme immunoassay kit for the detection and quantification of IgG to hepatitis A virus	D-0362
2.	VectoMeasles-IgG	Enzyme immunoassay kit for the detection and quantification of IgG to measles virus in blood serum (plasma)	D-1356
3.	VectoMeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma)	D-1358
4.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen	D-1652
5.	Adenovirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen	D-1654
6.	VectoEBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to Epstein-Barr virus nuclear antigen in blood serum (plasma)	D-2170
7.	VectoEBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to Epstein-Barr virus early antigens in blood serum (plasma)	D-2172
8.	VectoEBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma)	D-2176
9.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma)	D-2602
10.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Toxocara antigens in blood serum (plasma)	D-2752
11.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Trichinella antigens in blood serum (plasma)	D-3152
12.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis	D-3202
13.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis	D-3204
14.	Yersinia-IgM-EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis	D-3206
15.	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Echinococcus granulosus antigens in blood serum (plasma)	D-3356
16.	Ascaris-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Ascaris lumbricoides antigens in blood serum (plasma)	D-3452
17.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantification of IgA to tissue transglutaminase in blood serum (plasma)	D-3758

18.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantification of IgG to tissue transglutaminase in blood serum (plasma)	D-3760
19.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the quantification of pepsinogen 1 in blood serum (plasma)	D-3762
20.	Pepsinogen 2-EIA-BEST	Enzyme immunoassay kit for the quantification of pepsinogen 2 in blood serum (plasma)	D-3764
21.	VectoHanta-IgG	Enzyme immunoassay kit for the detection of IgG to hantavirus in blood serum (plasma)	D-4902
22.	VectoHanta-IgM	Enzyme immunoassay kit for the detection of IgM to hantavirus in blood serum (plasma)	D-4904
23.	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile virus in blood serum (plasma)	D-5150
24.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile virus in blood serum (plasma)	D-5152
25.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of avidity index of IgG to West Nile virus in blood serum (plasma)	D-5154
26.	VectoCrimean-CHF-IgG	Enzyme immunoassay kit for the detection of IgG to Crimean-Congo hemorrhagic fever virus in blood serum (plasma)	D-5052
27.	VectoCrimean-CHF-IgM	Enzyme immunoassay kit for the detection of IgM to Crimean-Congo hemorrhagic fever virus in blood serum (plasma)	D-5054
28.	VectoCrimean-CHF-antigen	Enzyme immunoassay kit for the detection of Crimean-Congo hemorrhagic fever virus antigen	D-5056

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System
No. 11 0040 QS/NB

The quality system of manufacturer

Federal Budget Institute of Science "Central Research Institute for Epidemiology"

3a Novogireevskaya Street, Moscow 111123, Russia

has been certified as meeting the requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex IV excluding (4, 6)

for the following product category(ies):

AmpliSens® PCR kits

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

Valid from: 2022-05-20
Valid until: 2025-05-26
First Issued: 2011-01-24
Revision: m

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION 4

Digitally signed by Ceaicovschi Tudor
Date: 2025.02.03 17:11:24 EET
Reason: MoldSign Signature
Location: MDelete
MOLDOVA EUROPEANĂ

Date: 2022-05-20

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Product(s):

Name:	**AmpliSens® *Rubella virus*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-50 F
Classification:	List B
GMDN:	30793
Name:	**AmpliSens® *Toxoplasma gondii*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-50 F
Classification:	List B
GMDN:	52428
Name:	**AmpliSens® *CMV*-FEP PCR kit**
Trade name(s):	-
Model(s):	variant FEP (0.2-ml tubes)
Classification:	List B
GMDN:	30798

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *CMV*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	30798
Name:	**AmpliSens® *HSV* / *CMV*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	61348
Name:	**AmpliSens® *CMV*-screen/monitor-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	30798

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *EBV / CMV / HHV6*-screen-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	61348
Name:	**AmpliSens® *Chlamydia trachomatis*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT, variant FRT-100 F
Classification:	List B
GMDN:	30677
Name:	**AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *C.trachomatis / Ureaplasma / M.hominis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409
Name:	**AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium / M.hominis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409
Name:	**AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium / T.vaginalis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409
Name:	**AmpliSens® Genoscreen HLA B*5701-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT
Classification:	List B
GMDN:	56403
Name:	**AmpliSens® *Mycoplasma pneumoniae / Chlamydophila pneumoniae*-FEP PCR kit**
Trade name(s):	-
Model(s):	variant FEP (0.2 ml tubes)
Classification:	List B
GMDN:	58957

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	58957
Name:	**AmpliSens® *T.vaginalis* / *N.gonorrhoeae* / *C.trachomatis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	61144
Name:	**AmpliSens® *HCV*-Monitor-L PCR kit**
Trade name(s):	-
Model(s):	variant FRT-L
Classification:	List A
GMDN:	48374

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *HBV*-Monitor-L PCR kit**
Trade name(s):	-
Model(s):	variant FRT-L
Classification:	List A
GMDN:	48307

Facility(ies):

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

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Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Certificate History:

Revision	Date	Reference Number	Action
	2011-01-24	813600111	Certification
a	2011-07-21	813600161	Change of manufacturer name
b	2012-02-13	343601304	Product scope extension
c	2014-05-13	343602568	Product scope extension
d	2016-01-15	813600504a	Prolongation of certificate validity
e	2016-06-17	813600504	Re-certification process
f	2016-08-29	343603690	Change of manufacturer facility address
g	2017-11-30	343603888	Changes of product compositions, packaging and quality system documentation
h	2018-10-31	813600754	Change of product labelling, shelf life extension and quality system documentation
i	2019-05-09	813600859	Product shelf life extension
j	2021-04-27	813601045	Re-certification process

Date: 2022-05-20
Revision: m

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

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INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
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Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Revision	Date	Reference Number	Action
k	2022-04-28	813601141	Extension of the certificate validity regarding to REGULATION (EU) 2022/112 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, dated 25th January 2022
l	2022-05-20	833600365	Product scope reduction
m	2022-05-20	813601116	Certification– List A IVD PCR kits

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

CERTIFICATE

TÜV AUSTRIA

Management system as per EN ISO 13485:2016

In accordance with TÜV AUSTRIA Standards & Compliance procedures,
it is hereby certified that

Federal Budget Institute of Science
«Central Research Institute of Epidemiology»
of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing
(FBIS CRIE of Rospotrebnadzor)
3a, Novogireevskaya str., 111123, Moscow
Russian Federation

Including:
3a, Novogireevskaya str., 111123, Moscow, Russian Federation
3a, bldg. 6, Novogireevskaya str., 111123, Moscow, Russian Federation

applies a management system in line with the above standard for the following scope

Design, development, production and final control of medical devices for in vitro diagnostics

Certificate Registration No. TASC-C-20230720001

Valid until: 2026-07-19
Initial certification: 2023-07-20

Digitally signed by Ceaicovschi Tudor
Date: 2025.02.03 17:14:42 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Certification authority
TÜV AUSTRIA Standards & Compliance

Moscow, 2023-07-20

STANDARDS & COMPLIANCE
conformity assessment based on ISO/IEC 17021-1:2015

Online Verification

This certification was conducted in accordance with auditing and certification procedures of TÜV AUSTRIA Standards & Compliance and is subject to annual surveillance audits.
TÜV AUSTRIA Standards & Compliance LTD, 12 Levoberezhnaya street, office 109, 125445, Moscow, Russian Federation

Validity of the certificate can be verified by request on general@tuv-austria.ru

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

СЕРТИФИКАТ

TÜV AUSTRIA

соответствия системы менеджмента требованиям стандарта EN ISO 13485:2016

в соответствии с процедурами TÜV AUSTRIA Standards & Compliance
настоящим подтверждается, что

Федеральное бюджетное учреждение науки «Центральный научно-исследовательский институт эпидемиологии» Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека (ФБУН ЦНИИ Эпидемиологии Роспотребнадзора)
ул. Новогиреевская, д.3А
111123, г. Москва, Российская Федерация

Включая:
ул. Новогиреевская, д.3А, 111123, г. Москва, Российская Федерация
ул. Новогиреевская, д.3А строение 6, 111123, г. Москва, Российская Федерация

применяет систему менеджмента, соответствующую вышеназванному стандарту в следующих областях:

Проектирование, разработка, производство и выходной контроль медицинских изделий для диагностики in vitro

Регистрационный номер No. TASC-C-20230720001

Действителен до : 2026-07-19
Дата первичной сертификации : 2023-07-20

Орган по сертификации
TÜV AUSTRIA Standards & Compliance

г. Москва, 2023-07-20

Digitally signed by Saraiovschi Tudor
Date: 2025.02.03 17:14:52 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

conformity assessment based on ISO/IEC 17021-1:2015

Online Verification

Данная сертификация проведена в соответствии с процедурами аудитирования и сертификации TÜV AUSTRIA Standards & Compliance и подлежит регулярным ежегодным надзорным аудитам.
ООО «ТЮФ АУСТРИЯ Стандарты и Соответствие», РФ, 125445, г. Москва, ул. Левобережная, д. 12, эт. 1, пом. 109

Validity of the certificate can be verified by request on general@tuv-austria.ru

FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE
FEDERAL BUDGET INSTITUTE OF SCIENCE
«CENTRAL RESEARCH INSTITUTE FOR EPIDEMIOLOGY»
111123, Moscow, 3A Novogireevskaya street, Tel.: +7 495 974 96 42, Fax: +7 495 305 54 23,
e-mail: obtk@pcr.ru

CE

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27th of October 1998 on *In Vitro* Diagnostic Medical Devices

Federal Budget Institute of Science "Central Research Institute for Epidemiology" hereby under own responsibility declares that the products covered by the declaration conform with Essential Requirements listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation is retained under the premises of the manufacturer.

The quality management system meets the requirements of the standard EN ISO 13485 "Medical devices – Quality management systems – Requirements for regulatory purposes" and is certified by Institute for testing and certification, Inc. (certificate No. 21 0023 SJ, valid until 26.04.2024).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorized Representative:	Ecoli Dx, s.r.o. Purkyňova 74/2 Praha 1, 110 00 Czech Republic Tel: +420 325 209 912 Cell: +420 739 802 523 E-mail: ecoli@ecoli.sk
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents or HLA B*5701 DNA in human specimens
Classification:	Article 9, paragraph 3 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices Annex II List B IVDs (According to EC Declaration of Conformity List)
Conformity Assessment Route:	Annex IV (IVDD) excluding (4, 6) Full QA System
Notified Body:	Institute for testing and certification, Inc. třida Tomáše Bati 299 Louky, 763 02 Zlin, Czech Republic E-mail: itc@itczlin.cz Notified Body No. 1023
EC Certificate:	No. 11 0040 QS/NB revision m, valid until 2025-05-26
Place, Date of Issue:	Zlin, Czech Republic, 2022-05-20

Digitally signed by Ceaicovschi Tudor
Date: 2025.02.03 17:11:12 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Signed

Full name: Vasiliy G. [illegible]
Title: Director

Valid from 2022-05-20

Valid until 2025-05-26

№№	Description	Model(s)
1.	**AmpliSens® *Rubella virus*-FRT** PCR kit	variant FRT-50 F
2.	**AmpliSens® *Toxoplasma gondii*-FRT** PCR kit	variant FRT-50 F
3.	**AmpliSens® *CMV*-FEP** PCR kit	variant FEP (0.2-ml tubes)
4.	**AmpliSens® *CMV*-FRT** PCR kit	variant FRT-100 F
5.	**AmpliSens® *HSV* / *CMV*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
6.	**AmpliSens® *CMV*-screen/monitor-FRT** PCR kit	variant FRT-100 F
7.	**AmpliSens® *EBV* / *CMV* / *HHV*6-screen-FRT** PCR kit	variant FRT-100 F
8.	**AmpliSens® *Chlamydia trachomatis*-FRT** PCR kit	variant FRT variant FRT-100 F
9.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.genitalium*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
10.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.hominis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
11.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.genitalium* / *M.hominis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
12.	**AmpliSens® *N.gonorrhoeae* / *C.trachomatis* / *M.genitalium* / *T.vaginalis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
13.	**AmpliSens® *N.gonorrhoeae* / *C.trachomatis* / *M.genitalium*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
14.	**AmpliSens® Genoscreen HLA B*5701-FRT** PCR kit	variant FRT
15.	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FEP** PCR kit	variant FEP (0.2-ml tubes)
16.	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FRT** PCR kit	variant FRT-100 F
17.	**AmpliSens® *T.vaginalis* / *N.gonorrhoeae* / *C.trachomatis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
(РОССТАНДАРТ)

**ФЕДЕРАЛЬНОЕ БЮДЖЕТНОЕ УЧРЕЖДЕНИЕ
«ГОСУДАРСТВЕННЫЙ РЕГИОНАЛЬНЫЙ ЦЕНТР СТАНДАРТИЗАЦИИ,
МЕТРОЛОГИИ И ИСПЫТАНИЙ В Г. МОСКВЕ И МОСКОВСКОЙ ОБЛАСТИ»
(ФБУ «РОСТЕСТ-МОСКВА»)**

ОРГАН ПО СЕРТИФИКАЦИИ СИСТЕМ МЕНЕДЖМЕНТА

РОСТЕСТ-МОСКВА

**АТТЕСТАТ АККРЕДИТАЦИИ №RA.RU.13PT02
ФЕДЕРАЛЬНОЙ СЛУЖБЫ ПО АККРЕДИТАЦИИ РФ**

СЕРТИФИКАТ СООТВЕТСТВИЯ

Выдан **ФБУН ЦНИИ Эпидемиологии Роспотребнадзора**
юридический адрес: 111123, Россия, г. Москва, ул. Новогиреевская, дом 3А;
адреса производств: 111123, Россия, г. Москва, ул. Новогиреевская, дом 3А;
111123, Россия, г. Москва, ул. Новогиреевская, дом 3А, стр.6.

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ:

система менеджмента качества применительно к разработке, производству и выходному контролю медицинских изделий для in vitro диагностики

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выпуск 2. СМК сертифицирована с сентября 2019г.

Разъяснения, касающиеся области сертификации СМК, могут быть получены путем консультаций с ФБУН ЦНИИ Эпидемиологии Роспотребнадзора

Регистрационный № RU CMS-RU.PT02.00301

Дата регистрации **04.05.2023** Срок действия до **20.09.2025**

Руководитель органа по сертификации систем менеджмента Ю.В. Егоров

Аудитор В.Л. Рыбачек

ФБУ «Ростест-Москва» RA.RU.13PT02

119234, г. Москва,
Ленинский проспект 31
+7 (495) 544-00-00
Quality@rostest.ru

Бланк №0200

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System
No. 11 0040 QS/NB

The quality system of manufacturer

Federal Budget Institute of Science "Central Research Institute for Epidemiology"

3a Novogireevskaya Street, Moscow 111123, Russia

has been certified as meeting the requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex IV excluding (4, 6)

for the following product category(ies):

AmpliSens® PCR kits

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

Valid from: 2022-05-20
Valid until: 2025-05-26
First Issued: 2011-01-24
Revision: m

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION 4

Date: 2022-05-20

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Product(s):

Name:	**AmpliSens® *Rubella virus*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-50 F
Classification:	List B
GMDN:	30793
Name:	**AmpliSens® *Toxoplasma gondii*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-50 F
Classification:	List B
GMDN:	52428
Name:	**AmpliSens® *CMV*-FEP PCR kit**
Trade name(s):	-
Model(s):	variant FEP (0.2-ml tubes)
Classification:	List B
GMDN:	30798

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

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Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *CMV*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	30798
Name:	**AmpliSens® *HSV* / *CMV*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	61348
Name:	**AmpliSens® *CMV*-screen/monitor-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	30798

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-05-20
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Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *EBV / CMV / HHV6*-screen-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	61348
Name:	**AmpliSens® *Chlamydia trachomatis*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT, variant FRT-100 F
Classification:	List B
GMDN:	30677
Name:	**AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

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Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *C.trachomatis / Ureaplasma / M.hominis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409
Name:	**AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium / M.hominis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409
Name:	**AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium / T.vaginalis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-05-20
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INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	50409
Name:	**AmpliSens® Genoscreen HLA B*5701-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT
Classification:	List B
GMDN:	56403
Name:	**AmpliSens® *Mycoplasma pneumoniae / Chlamydophila pneumoniae*-FEP PCR kit**
Trade name(s):	-
Model(s):	variant FEP (0.2 ml tubes)
Classification:	List B
GMDN:	58957

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

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Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	58957
Name:	**AmpliSens® *T.vaginalis* / *N.gonorrhoeae* / *C.trachomatis*-MULTIPRIME-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT-100 F
Classification:	List B
GMDN:	61144
Name:	**AmpliSens® *HCV*-Monitor-L PCR kit**
Trade name(s):	-
Model(s):	variant FRT-L
Classification:	List A
GMDN:	48374

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

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INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Name:	**AmpliSens® *HBV*-Monitor-L PCR kit**
Trade name(s):	-
Model(s):	variant FRT-L
Classification:	List A
GMDN:	48307

Facility(ies):

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Certificate History:

Revision	Date	Reference Number	Action
	2011-01-24	813600111	Certification
a	2011-07-21	813600161	Change of manufacturer name
b	2012-02-13	343601304	Product scope extension
c	2014-05-13	343602568	Product scope extension
d	2016-01-15	813600504a	Prolongation of certificate validity
e	2016-06-17	813600504	Re-certification process
f	2016-08-29	343603690	Change of manufacturer facility address
g	2017-11-30	343603888	Changes of product compositions, packaging and quality system documentation
h	2018-10-31	813600754	Change of product labelling, shelf life extension and quality system documentation
i	2019-05-09	813600859	Product shelf life extension
j	2021-04-27	813601045	Re-certification process

Date: 2022-05-20
Revision: m

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a Novogireevskaya Street, Moscow 111123, Russia

Revision	Date	Reference Number	Action
k	2022-04-28	813601141	Extension of the certificate validity regarding to REGULATION (EU) 2022/112 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, dated 25th January 2022
l	2022-05-20	833600365	Product scope reduction
m	2022-05-20	813601116	Certification– List A IVD PCR kits

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20
Revision: m

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

CERTIFICATE

TÜV AUSTRIA

Management system as per
EN ISO 13485:2016

In accordance with TÜV AUSTRIA Standards & Compliance procedures,
it is hereby certified that

Federal Budget Institute of Science «Central Research Institute of Epidemiology» of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (FBIS CRIE of Rospotrebnadzor)

3a, Novogireevskaya str., 111123, Moscow
Russian Federation

Including:
3a, Novogireevskaya str., 111123, Moscow, Russian Federation
3a, bldg. 6, Novogireevskaya str., 111123, Moscow, Russian Federation

applies a management system in line with the above standard for the following scope

Design, development, production and final control of medical devices for in vitro diagnostics

Certificate Registration No. TASC-C-20230720001

Valid until: 2026-07-19
Initial certification: 2023-07-20

Certification authority
TÜV AUSTRIA Standards & Compliance

Moscow, 2023-07-20

STANDARDS & COMPLIANCE
conformity assessment based on ISO/IEC 17021-1:2015

Online Verification

This certification was conducted in accordance with auditing and certification procedures of TÜV AUSTRIA Standards & Compliance and is subject to annual surveillance audits.
TÜV AUSTRIA Standards & Compliance LTD, 12 Levoberezhnaya street, office 109, 125445, Moscow, Russian Federation

Validity of the certificate can be verified by request on general@tuv-austria.ru

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

СЕРТИФИКАТ

TÜV AUSTRIA

соответствия системы менеджмента требованиям стандарта EN ISO 13485:2016

в соответствии с процедурами TÜV AUSTRIA Standards & Compliance
настоящим подтверждается, что

Федеральное бюджетное учреждение науки «Центральный научно-исследовательский институт эпидемиологии» Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека (ФБУН ЦНИИ Эпидемиологии Роспотребнадзора)

ул. Новогиреевская, д.3А
111123, г. Москва, Российская Федерация

Включая:
ул. Новогиреевская, д.3А, 111123, г. Москва, Российская Федерация
ул. Новогиреевская, д.3А строение 6, 111123, г. Москва, Российская Федерация

применяет систему менеджмента, соответствующую вышеназванному стандарту в следующих областях:

Проектирование, разработка, производство и выходной контроль медицинских изделий для диагностики in vitro

Регистрационный номер No. TASC-C-20230720001

Действителен до : 2026-07-19
Дата первичной сертификации : 2023-07-20

Орган по сертификации
TÜV AUSTRIA Standards & Compliance

г. Москва, 2023-07-20

STANDARDS & COMPLIANCE
conformity assessment based on ISO/IEC 17021-1:2015

Online Verification

Данная сертификация проведена в соответствии с процедурами аудитирования и сертификации TÜV AUSTRIA Standards & Compliance и подлежит регулярным ежегодным надзорным аудитам.
ООО «ТЮФ АУСТРИЯ Стандарты и Соответствие», РФ, 125445, г. Москва, ул. Левобережная, д. 12, эт. 1, пом. 109

Validity of the certificate can be verified by request on general@tuv-austria.ru

FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE
FEDERAL BUDGET INSTITUTE OF SCIENCE
«CENTRAL RESEARCH INSTITUTE FOR EPIDEMIOLOGY»
111123, Moscow, 3A Novogireevskaya street, Tel.: +7 495 974 96 42, Fax: +7 495 305 54 23,
e-mail: obtk@pcr.ru

CE

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27th of October 1998 on *In Vitro* Diagnostic Medical Devices

Federal Budget Institute of Science "Central Research Institute for Epidemiology" hereby under own responsibility declares that the products covered by the declaration conform with Essential Requirements listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation is retained under the premises of the manufacturer.

The quality management system meets the requirements of the standard EN ISO 13485 "Medical devices – Quality management systems – Requirements for regulatory purposes" and is certified by Institute for testing and certification, Inc. (certificate No. 21 0023 SJ, valid until 26.04.2024).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorized Representative:	Ecoli Dx, s.r.o. Purkyňova 74/2 Praha 1, 110 00 Czech Republic Tel: +420 325 209 912 Cell: +420 739 802 523 E-mail: ecoli@ecoli.sk
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents or HLA B*5701 DNA in human specimens
Classification:	Article 9, paragraph 3 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices Annex II List B IVDs (According to EC Declaration of Conformity List)
Conformity Assessment Route:	Annex IV (IVDD) excluding (4, 6) Full QA System
Notified Body:	Institute for testing and certification, Inc. třida Tomáše Bati 299 Louky, 763 02 Zlin, Czech Republic E-mail: itc@itczlin.cz Notified Body No. 1023
EC Certificate:	No. 11 0040 QS/NB revision m, valid until 2025-05-26
Place, Date of Issue:	Zlin, Czech Republic, 2022-05-20

Signed _____ Valid from 2022-05-20

Full name: Vasiliy G. Akimkin Valid until 2025-05-26
Title: Director

№№	Description	Model(s)
1.	**AmpliSens® *Rubella virus*-FRT** PCR kit	variant FRT-50 F
2.	**AmpliSens® *Toxoplasma gondii*-FRT** PCR kit	variant FRT-50 F
3.	**AmpliSens® *CMV*-FEP** PCR kit	variant FEP (0.2-ml tubes)
4.	**AmpliSens® *CMV*-FRT** PCR kit	variant FRT-100 F
5.	**AmpliSens® *HSV* / *CMV*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
6.	**AmpliSens® *CMV*-screen/monitor-FRT** PCR kit	variant FRT-100 F
7.	**AmpliSens® *EBV* / *CMV* / *HHV*6-screen-FRT** PCR kit	variant FRT-100 F
8.	**AmpliSens® *Chlamydia trachomatis*-FRT** PCR kit	variant FRT variant FRT-100 F
9.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.genitalium*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
10.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.hominis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
11.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.genitalium* / *M.hominis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
12.	**AmpliSens® *N.gonorrhoeae* / *C.trachomatis* / *M.genitalium* / *T.vaginalis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
13.	**AmpliSens® *N.gonorrhoeae* / *C.trachomatis* / *M.genitalium*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
14.	**AmpliSens® Genoscreen HLA B*5701-FRT** PCR kit	variant FRT
15.	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FEP** PCR kit	variant FEP (0.2-ml tubes)
16.	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FRT** PCR kit	variant FRT-100 F
17.	**AmpliSens® *T.vaginalis* / *N.gonorrhoeae* / *C.trachomatis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F