

Product List – CE Marked

Certified by

ISO 13485:2016

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

2020-02-1

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 simplex 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	Corynebacterium 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
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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
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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
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DNOV010	Urinary Cortisol
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STEROID HORMONES IN SALIVA

(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
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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
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DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovaLisa[®] Autoimmune

Autoimmune

(ELISAs for the determination of specific autoimmune antibodies)

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

Rheumatology

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

Prod. No.	Name
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RFM3010	Rheumatoid Factor IgM
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NovaLisa[®] Recombinant Antigens

Prod. No.	Name
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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 simplex 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	Corynebacterium 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
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NS1D4020	Dengue Virus NS1 Antigen
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NovaLisa[®] IgM μ -capture Assays

Prod. No.	Name
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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
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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
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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



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:

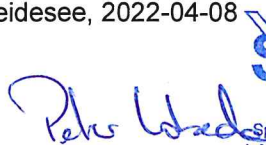
Seramun Diagnostica GmbH, Spreenhagener Straße 1, 15754 Heidesee, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices, that the following products fulfill the basic requirements 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
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

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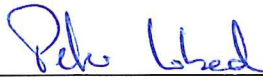
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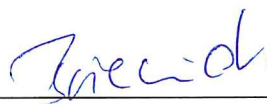
Produktgruppe / Product Group:

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


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Geschäftsführung /
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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


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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
Seramun Diagnostica GmbH
Spreehagener Straße 1, 15754 Heidesee, Germany
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Geschäftsführung /
Managing Director



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Deputy Director of Regulatory Affairs

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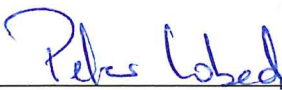
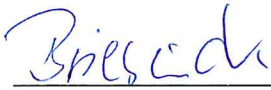
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Produktgruppe / Product Group:

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 Sreenhagener Str. 1 • 15754 Heidesee info@seramun.com • T +49 33767 791 10	 Michaela Briesenick Stellv. Abteilungsleitung Regulatory Affairs / Deputy Director of Regulatory Affairs
Peter Lobeda Geschäftsführung / Managing Director	

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Seramun Diagnostica GmbH, Sreenhagener 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, Sreenhagener 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, Sreenhagener 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
Sreenhagener 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.

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	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

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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

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

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

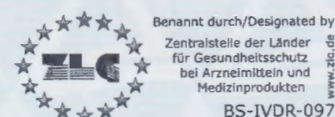
The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined 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.

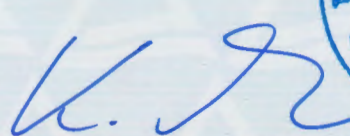
Report No.: 1090492-40

Effective date: 2023-05-10

Expiry date: 2028-05-09

Issue date: 2023-05-10




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

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
Effective date: 2023-05-10
Expiry date: 2028-05-09
Issue date: 2023-05-10



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

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

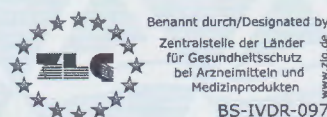
IVR 0501: Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents
W0201020192 - AUTOMATED IMMUNOCHEMISTRY ANALYSERS – IVD MEDICAL DEVICE SOFTWARE

Report No.: 1090492-40

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Katja Mierisch
TÜV Rheinland LGA Products GmbH
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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


TÜVRheinland

Report No.: 1090492-40
Effective date: 2023-05-10
Expiry date: 2028-05-09
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Katja Mierisch
TÜV Rheinland LGA Products GmbH
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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

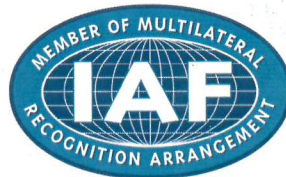
**Проектирование, разработка и производство медицинских изделий для
диагностики in vitro (ИФА)**

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



	AO Vector-Best	Rev. 2
	EC Declaration of conformity ELISA	Page 1 of 3

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

Valid until: 2022/07/03



Murat Khusainov
General Director AO Vector-Best

	AO Vector-Best	Rev. 2
	EC Declaration of conformity ELISA	Page 2 of 3

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

	AO Vector-Best	Rev. 2
	EC Declaration of conformity ELISA	Page 3 of 3

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

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



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: NF9QKDG9EA



CORREO ELECTRÓNICO
secretariaCNCps@certificaps.gob.es

Página 1 de 1

C/ CAMPEZO, 1 - EDIFICIO 7
28022 MADRID
Tel.: (+34) 91 822 5130

CERTIFICACIÓN 13485

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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ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
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ANEXO N°/ANNEX NO: I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
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Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/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) Descrito en el certificado/ Described in the certificate 2006 11 0511 ED
- SCONF.CE.40 (40 tests)

1.6. HBs Ag one Version ULTRA

- SAG1ULTRA.CE (192 tests) Descrito en el certificado/ Described in the certificate 2008 12 0588 ED
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests)

1.7. HCV Ab

- CVAB.CE (192 tests) Descrito en el certificado/ Described in the certificate 2003 12 0392 ED
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests)

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

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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

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 19/05/2022

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2.3 HDV ONESTEP Quantitation (QT)

- HDVONEQT.CE (50 tests) Descrito en el certificado/ Described in the certificate 2022 04 0973 ED
- HDVONEQT.CE.25 (25 tests)
- HDVONEQT.CE.100 (100 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 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

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 19/05/2022

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ANEXO N°/ANNEX NO: I

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	20-05-2022	26-05-2025	

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

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 19/05/2022

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ORGANISMO NOTIFICADO 0318

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CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
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Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/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 n° 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 n° 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
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Fdo. Mª Jesús Lamas Díaz

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ANEXO N°/ANNEX NO: I

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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)

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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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)

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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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)

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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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)

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 19/05/2022

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CSV: B 8 B Q W K 2 5 B 8



CORREO ELECTRÓNICO
on0318@aemps.es

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ORGANISMO NOTIFICADO 0318

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28022 MADRID
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ANEXO N°/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 n°/Certificate no	Fecha de validez/Date of validity		ON n°/NB no
2004 05 0442 CT	Desde/From	Hasta/To	0318
	20-05-2022	26-05-2025	

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. M^a Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 19/05/2022

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