

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
 Waldstraße 23 A6  
 63128 Dietzenbach  
 Germany

herewith declare under our own responsibility, that the product

### **NovaLisa® Borrelia burgdorferi IgG (BORG0040)**

and the following components:

<b>MTP</b>	Microtiterplate
<b>DIL G</b>	IgG Sample Dilution Buffer
<b>SOLN STOP</b>	Stop Solution
<b>WASH BUF 20x</b>	Washing Buffer (20x conc.)
<b>CONJ</b>	Conjugate
<b>SUB TMB</b>	TMB Substrate Solution
<b>CONTROL -</b>	Negative Control
<b>CUT OFF</b>	Cut-off Control
<b>CONTROL +</b>	Positive Control

is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in  
**Annex III (2-5)**

Dietzenbach      2020.07.21

  
 \_\_\_\_\_  
 Jennifer Völger  
 Quality Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
 Waldstraße 23 A6  
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### **NovaLisa® Borrelia burgdorferi IgM (BORM0040)**

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# 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



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>

For electronic publication only

**Attachment of the certificate**

**No. D1055500019**

Date 2022-05-03

Page 1 of 1

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

  
 Head of Certification Body



# Product List – CE Marked

Certified by

ISO 13485:2016

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

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2020-02-1

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**NovaLisa® Virology**

<b>Prod. No.</b>	<b>Name</b>
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM $\mu$ -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 $\mu$ -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 $\mu$ -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 $\mu$ -capture

**NovaLisa<sup>®</sup> Bacteriology**

<b>Prod. No.</b>	<b>Name</b>
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
PELG022	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**

<b>Prod. No.</b>	<b>Name</b>
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 $\mu$ -capture

**NovaLisa® Worms**

<b>Prod. No.</b>	<b>Name</b>
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**

<b>Prod. No.</b>	<b>Name</b>
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)**

<b>Prod. No.</b>	<b>Name</b>
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)**

<b>Prod. No.</b>	<b>Name</b>
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)**

<b>Prod. No.</b>	<b>Name</b>
DNOV010	Urinary Cortisol

### **STEROID HORMONES IN SALIVA**

**(ELISAs for the determination of steroid hormones in saliva)**

<b>Prod. No.</b>	<b>Name</b>
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)**

<b>Prod. No.</b>	<b>Name</b>
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

**THYROID HORMONES**

**(ELISAs for the determination of thyroid hormones and antibodies)**

<b>Prod. No.</b>	<b>Name</b>
DNOV051	Free T3
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

**DIABETES MONITORING**

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

<b>Prod. No.</b>	<b>Name</b>
DNOV111	Insulin
DNOV112	C-Peptide

**CIRCULATING IMMUNO COMPLEXES**

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

<b>Prod. No.</b>	<b>Name</b>
DNOV093	CIC-C1q
DNOV094	CIC-C3d
DNOV096	CH-50

**TUMOR MARKERS**

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

<b>Prod. No.</b>	<b>Name</b>
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)

<b>Prod. No.</b>	<b>Name</b>
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DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

## **NovoLisa<sup>®</sup> Autoimmune**

### Autoimmune

(ELISAs for the determination of specific autoimmune antibodies)

<b>Prod. No.</b>	<b>Name</b>
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ATG1010	Anti-TG
ATPO1020	Anti-TPO

### Rheumatology

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

<b>Prod. No.</b>	<b>Name</b>
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RFM3010	Rheumatoid Factor IgM
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## **NovoLisa<sup>®</sup> Recombinant Antigens**

<b>Prod. No.</b>	<b>Name</b>
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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 $\mu$ -capture

## **NovaLisa<sup>®</sup> Quantitative Assays (WHO standardized)**

<b>Prod. No.</b>	<b>Name</b>
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<sup>®</sup> Quantitative Assays**

<b>Prod. No.</b>	<b>Name</b>
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<sup>®</sup> IgM $\mu$ -capture Assays

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

## NovaLisa<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>      Liquor Diagnostic**

<b>Prod. No.</b>	<b>Name</b>
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM