

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	2016-10-26
Valid until	2018-12-03
Registration no.	D1055500012
Report no.	P16-01416-82188
Stuttgart	2016-10-26

Head of Certification Body



Attachment of the certificate

No. D1055500012

Date 2016-10-26

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



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