

Conformity Declaration

We

NovaTec Immundiagnostica GmbH

Waldstr. 23 A6 , 63128 Dietzenbach

herewith declare under our own responsibility, that the product

Novagnost™ Ascaris lumbricoides IgG (ASCG0020DB)

according to article 9 paragraph 1 with the purpose of qualitative in vitro determination of antibodies to *Ascaris lumbricoides* in serum by using photometric systems, 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).

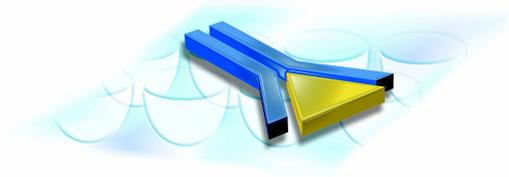
The accordance was shown by conformity assessment procedures in

Annex III (II – V)

A handwritten signature in blue ink, appearing to read 'C. Rezmer', with a long horizontal flourish extending to the right.

Dietzenbach 2006-04-10

Dr. Claudia Rezmer
Product Management



Conformity Declaration

We

NovaTec Immundiagnostica GmbH

Waldstr. 23 A6 , 63128 Dietzenbach

herewith declare under our own responsibility, that the product

Novagnost™ Chlamydia pneumoniae IgG (CHLG0510DB)

of list B annex II with the purpose of qualitative in vitro determination of Chlamydia pneumoniae antibodies in serum by using photometric systems, is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct.27,1988 in regard to in vitro diagnostic medical devices (IVDs).

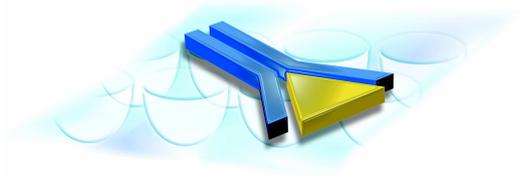
The accordance was shown by conformity assessment procedures in

Annex IV

by participation of the notified body MDC-Medical Device Certification (0483).

Dietzenbach 2005-10-12

Dr. Claudia Rezmer
Product Management



Conformity Declaration

We

NovaTec Immundiagnostica GmbH

Waldstr. 23 A6, 63128 Dietzenbach

herewith declare under our own responsibility, that the product

Novagnost™ Chlamydia pneumoniae IgM (CHLM0510DB)

of list B annex II with the purpose of qualitative in vitro determination of Chlamydia pneumoniae antibodies in serum by using photometric systems, is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct.27, 1988 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

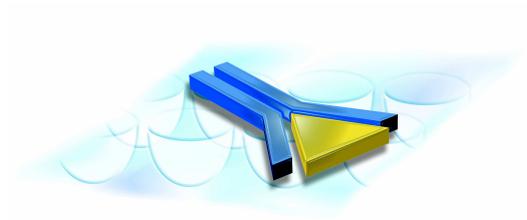
Annex IV

by participation of the notified body MDC-Medical Device Certification (0483).

Dietzenbach 2005-10-12

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Dr. Claudia Rezmer
Product Management



Conformity Declaration

We

NovaTec Immundiagnostica GmbH

Waldstr. 23 A6 , 63128 Dietzenbach

herewith declare under our own responsibility, that the product

Novagnost™ Mycoplasma pneumoniae IgG (MYCG0350DB)

according to article 9 paragraph 1 with the purpose of qualitative in vitro determination of antibodies to Mycoplasma pneumoniae in serum by using photometric systems, is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct.27,1988 in regard to in vitro diagnostic medical devices (IVDs).

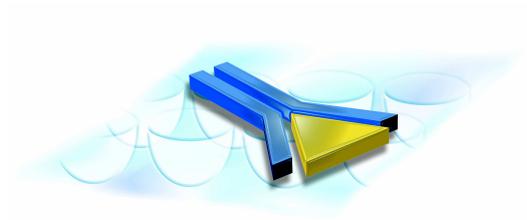
The accordance was shown by conformity assessment procedures in

Annex III (II – V)

Dietzenbach 2005-08-04

A handwritten signature in blue ink that reads "C. Rezmer" followed by a horizontal line.

Dr. Claudia Rezmer
Product Management



Conformity Declaration

We

NovaTec Immundiagnostica GmbH

Waldstr. 23 A6 , 63128 Dietzenbach

herewith declare under our own responsibility, that the product

Novagnost™ Mycoplasma pneumoniae IgM (MYCM0350DB)

according to article 9 paragraph 1 with the purpose of qualitative in vitro determination of antibodies to Mycoplasma pneumoniae in serum by using photometric systems, is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct.27,1988 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

Annex III (II – V)

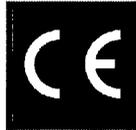
Dietzenbach 2005-08-19

A handwritten signature in blue ink, appearing to read 'C. Rezmer', with a long horizontal flourish extending to the right.

Dr. Claudia Rezmer
Product Management

Konformitätserklärung

Declaration of Conformity



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Anhang III erfüllt werden.

We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III .

Produktname (deutsch):

Enzygnost Anti-Helicobacter pylori II/IgG

Product name (English):

Enzygnost Anti-Helicobacter pylori II/IgG

Produkt-Nr. / Product No. (REF):

OQOA

Packungsgröße(n) / Package Size(s) (REF):

OQOA 11

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Dade Behring Marburg GmbH

Adresse (innerhalb Deutschland):

Dade Behring Marburg GmbH
Emil-von-Behring-Str. 76
35041 Marburg

Address (international):

Dade Behring Marburg GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Bestätigung / Authorization:

Leiter von Quality Assurance / Regulatory Affairs
Head of Quality Assurance / Regulatory Affairs

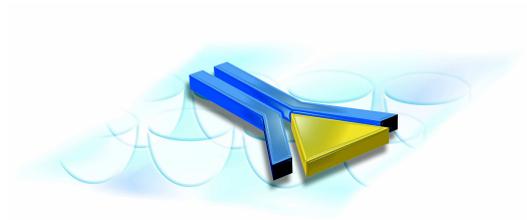
Unterschrift / Signature

Peter Shearstone

Name / Name

2006-03-14

Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:



Conformity Declaration

We

NovaTec Immundiagnostica GmbH

Waldstr. 23 A6 , 63128 Dietzenbach

herewith declare under our own responsibility, that the product

Novagnost™ Toxocara canis IgG (TOCG0450DB)

according to article 9 paragraph 1 with the purpose of qualitative in vitro determination of antibodies to *Toxocara canis* in serum by using photometric systems, 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 (II – V)

Dietzenbach 2006-04-10

A handwritten signature in blue ink, appearing to read 'C. Rezmer', with a long horizontal flourish extending to the right.

Dr. Claudia Rezmer
Product Management



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.

We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.

Produktname (deutsch):

BEP 2000 System / BEP 2000 Advance System

Product name (English):

BEP 2000 System / BEP 2000 Advance System

Produkt-Nr. / Product No. (REF):

OVMU

Konfiguration(en) / Configuration(s):

OVMU 11

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]: