

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

herewith declare under our own responsibility, that the product

### **NovaLisa® Chlamydia trachomatis IgG (CHLG0070)**

and the following components:

<b>MTP</b>	Chlamydia trachomatis Coated Microplate (IgG)
<b>DIL   G</b>	IgG Sample Diluent
<b>SOLN   STOP</b>	Stop Solution
<b>WASH   BUF   20x</b>	Washing Buffer (20x conc.)
<b>CONJ</b>	Chlamydia trachomatis anti-IgG Conjugate
<b>SUB   TMB</b>	TMB Substrate Solution
<b>CONTROL   -</b>	Chlamydia trachomatis IgG Negative control
<b>CUT OFF</b>	Chlamydia trachomatis IgG Cut-off control
<b>CONTROL   +</b>	Chlamydia trachomatis IgG Positive control

of annex II list B are 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 IV.3**

by participation of the notified body:

mdc medical device certification GmbH (0483)  
Kriegerstrasse 6  
70191 Stuttgart.

valid until: 2023-12-03

Dietzenbach 2018-11-19

  
Dr. Claudia Rezmer  
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.