

## 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>	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

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 2020.07.22

  
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.