

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

herewith declare under our own responsibility, that the product

### **NovaLisa® Mycoplasma pneumoniae IgG (MYCG0350)**

and the following components:

<b>MTP</b>	Mycoplasma pneumoniae 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>	Mycoplasma pneumoniae anti-IgG Conjugate
<b>SUB TMB</b>	TMB Substrate Solution
<b>CONTROL -</b>	Mycoplasma pneumoniae IgG Negative Control
<b>CUT OFF</b>	Mycoplasma pneumoniae IgG Cut-off Control
<b>CONTROL +</b>	Mycoplasma pneumoniae IgG 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 2019-02-18



Britta-Maria Duchmann Berlie  
Chief Operations Officer

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