

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

herewith declare under our own responsibility, that the product

**NovaLisa<sup>®</sup> Helicobacter pylori IgA Plus (PHELA022)**

and the following components:

<b>MTP</b>	Microtiterplate
<b>DIL A</b>	IgA 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>CAL A - D</b>	Standards A-D
<b>CONTROL</b>	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      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.