

## 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> Anti-TPO (ATPO1020)**

and the following components:

<b>MTP</b>	TPO 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>	TPO anti-IgG Conjugate
<b>SUB   TMB</b>	TMB Substrate Solution
<b>CONTROL   L</b>	Control Low
<b>CONTROL   H</b>	Control High
<b>CAL   A - F</b>	Anti- TPO Standards

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.