

## 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> Hepatitis E Virus (HEV) IgM (HEVM0780)**

and the following components:

<b>MTP</b>	Microtiterplate
<b>CONJ</b>	Conjugate
<b>CONTROL +</b>	Positive Control
<b>CONTROL -</b>	Negative Control
<b>CUT OFF</b>	Cut-off Control
<b>WASH BUF 20x</b>	Washing Buffer (20x conc.)
<b>SOLN STOP</b>	Stop Solution
<b>SUB TMB</b>	TMB Substrate Solution
<b>DIL M</b>	IgM Sample Dilution Buffer

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.

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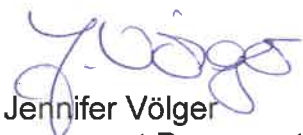
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