

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
 Waldstraße 23 A6  
 63128 Dietzenbach  
 Germany

herewith declare under our own responsibility, that the product

### **NovaLisa® 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)**

valid until: 2026-05-25

Dietzenbach 2022-09-06



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.