NovaTec
Immundiagnostica GmbH

# 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) IgG (HEVG0780)

and the following components:

| | |
|---|---|
| MTP | Microtiterplate |
| CONJ | Conjugate |
| CONTROL + | Positive Control |
| CONTROL - | Negative Control |
| CUT OFF | Cut-off Control |
| WASH BUF 20x | Washing Buffer (20x conc.) |
| SOLN STOP | Stop Solution |
| SUB TMB | TMB Substrate Solution |
| DIL G | IgG 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.