

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

herewith declare under our own responsibility, that the product

**NovaLisa® Herpes simplex Virus 1 (HSV 1) IgM (HSV1M0500)**

and the following components:

|                     |                            |
|---------------------|----------------------------|
| <b>MTP</b>          | Microtiterplate            |
| <b>DIL M</b>        | IgM 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>CONTROL -</b>    | Negative Control           |
| <b>CUT OFF</b>      | Cut-off Control            |
| <b>CONTROL +</b>    | Positive 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.

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

herewith declare under our own responsibility, that the product

**NovaLisa® Herpes simplex Virus 1 (HSV 1) IgG (HSV1G0500)**

and the following components:

|                     |                            |
|---------------------|----------------------------|
| <b>MTP</b>          | Microtiterplate            |
| <b>DIL G</b>        | IgG 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>CONTROL -</b>    | Negative Control           |
| <b>CUT OFF</b>      | Cut-off Control            |
| <b>CONTROL +</b>    | Positive 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.

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

herewith declare under our own responsibility, that the product

**NovaLisa® Herpes simplex Virus 2 (HSV 2) IgM (HSV2M0540)**

and the following components:

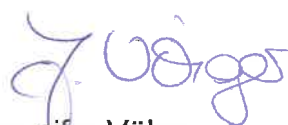
|                     |                            |
|---------------------|----------------------------|
| <b>MTP</b>          | Microtiterplate            |
| <b>DIL M</b>        | IgM Sample Dilution Buffer |
| <b>SOLN STOP</b>    | Stop Solution              |
| <b>WASH BUF 20x</b> | Washing Buffer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

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

herewith declare under our own responsibility, that the product

**NovaLisa® Herpes simplex Virus 2 (HSV 2) IgG (HSV2G0540)**

and the following components:

|                     |                            |
|---------------------|----------------------------|
| <b>MTP</b>          | Microtiterplate            |
| <b>DIL G</b>        | IgG 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>CONTROL -</b>    | Negative Control           |
| <b>CUT OFF</b>      | Cut-off Control            |
| <b>CONTROL +</b>    | Positive 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.