

## Declaration of Conformity

We NovaTec Immundiagnostica GmbH  
 Waldstraße 23 A6  
 63128 Dietzenbach  
 Germany

herewith declare under our own responsibility, that the product

### LH (DNOV030)

and the following components:


<b>MTP</b>	Coated Wells
<b>CONJ</b>	Anti-LH-HRP Conjugate + Anti LH-Biotin Conjugate
<b>SUB TMB</b>	TMB Substrate Solution
<b>WASH BUF 50x</b>	Wash Solution 50x conc.
<b>CONTROL</b>	LH Control
<b>CAL 0 - 5</b>	LH Standards 0-5
<b>SOLN STOP</b>	Stop Solution

are 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: 2018-11-21

  
 Dr. Claudia Rezmer  
 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.