

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
 Waldstraße 23 A6
 63128 Dietzenbach
 Germany

herewith declare under our own responsibility, that the product

Prolactin (DNOV032)

and the following components:

| | |
|---------------------|------------------------------|
| MTP | Microplate |
| CONJ | Anti-Prolactin-HRP Conjugate |
| SUB TMB | TMB Substrate Solution |
| WASH BUF 10x | Wash Solution 10x conc. |
| CONTROL | Prolactin Control |
| CAL 0 - 5 | Prolactin Standards 0-5 |
| SOLN STOP | 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.