

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

CEA (DNOV060)

and the following components:

| | |
|---------------------|-------------------------|
| MTP | Coated Wells |
| CONJ | Conjugate |
| SUB TMB | TMB Substrate Solution |
| WASH BUF 50x | Wash solution 50x conc. |
| CAL 0 - 5 | 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: 2018-11-22


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.