

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

CA 19-9 (DNOV063)

and the following components:

MTP	Coated Wells
CONJ	Conjugate
SUB TMB	TMB Substrate Solution
WASH BUF 10x	Wash Solution 10x conc.
CONTROL	CA 19-9 Control
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.