NovaTec Immundiagnostica GmbH

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

NovaLisa® SARS-CoV-2 (COVID-19) IgM (COVM0940)

and the following components:

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

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 2020-04-16

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 essential requirements.