

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

GSD NovaPrime[®] SARS-CoV-2 (COVID-19)

Product codes: PCOV6033 – 96 determinations
PCOV6034 – 4x 96 determinations

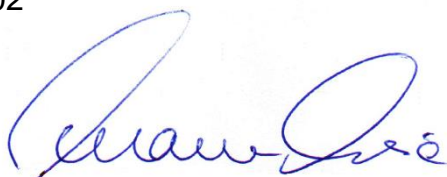
and the following components:

E-MIX	RT-PCR Enzyme Mix
PP	Primer-Probe-Mix
EC	Extraction Control
PC	Positive Control
NFW	Nuclease Free Water

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 2020-06-02



Britta-Maria Duchmann Berlie
Managing Director of Operations

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.