# Certificate

#### mdc medical device certification GmbH

certifies that



### NovaTec Immundiagnostica GmbH Waldstraße 23 A6 63128 Dietzenbach Germany

for the scope

development, manufacturing and distribution of in-vitro diagnostics (ELISA, Immunoblot, PCR)

has introduced and applies a

## **Quality Management System**

The mdc audit has proven that this quality management system meets all requirements of the following standard

#### **EN ISO 13485**

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

 Valid from Valid until
 2018-12-04

 Valid until
 2021-12-03

 Registration no.
 D1055500014

 Report no.
 P18-00810-122884

Stuttgart 2018-10-09

Head of Certification Body





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