

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	2018-12-04
Valid until	2021-12-03
Registration no.	D1055500014
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Stuttgart	2018-10-09



Head of Certification Body

