

Certificate

mdc medical device certification GmbH
certifies that



**Neuendorfstraße 17
16761 Hennigsdorf
Germany**

with the locations listed in the attachment

for the scope

**development, production and distribution of immunodiagnostic tests (IVD),
as well as contract development and production of calibration and control materials,
reagents, reagent products and kits for in vitro diagnostics**

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	2020-02-19
Valid until	2023-02-18
Registration no.	D1407800008
Report no.	P19-00615-145983
Stuttgart	2020-02-19

Head of Certification Body



Attachment of the certificate

No. D1407800008

date 2020-02-19

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Location	Scope
in.vent Diagnostica GmbH, Neuendorfstraße 17, 16761 Hennigsdorf	development, production and distribution of immunodiagnostic tests (IVD), as well as contract development and production of calibration and control materials, reagents, reagent products and kits for in vitro diagnostics
in.vent Diagnostica GmbH, Neuendorfstraße 17A, 16761 Hennigsdorf	development, production and distribution of immunodiagnostic tests (IVD), as well as contract development and production of calibration and control materials, reagents, reagent products and kits for in vitro diagnostics
in.vent Diagnostica GmbH, Neuendorfstraße 21, 16761 Hennigsdorf	manufacturing (storage of packaging materials, shipment)



Head of Certification Body