

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),
performance of clinical studies related to 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:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-02-19
Valid until	2026-02-18
Registration no.	D1407800013
Report no.	P22-01127-242267
Stuttgart	2022-12-19


Head of Certification Body



Attachment of the certificate

No. D1407800013

date 2022-12-19

Page 1 of 1

Location	Scope
in.vent Diagnostica GmbH Neuendorfstraße 17, 16761 Hennigsdorf	development, production and distribution of immunodiagnostic tests (IVD), performance of clinical studies related to 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 Am Postplatz 3a, 16761 Hennigsdorf	performance of clinical studies related to IVD
in.vent Diagnostica GmbH Horst-Müller-Strasse 9, 16761 Hennigsdorf	production (storage of calibration and control materials, reagents, reagent products and kits for in vitro diagnostics)




Head of Certification Body

Certificate

mdc medical device certification GmbH
certifies that



**Neuendorfstraße 17
16761 Hennigsdorf
Germany**

with the locations listed in the attachment

for the scope

**procurement, processing and provision of
human biological materials, conducting of diagnostic studies as well as
research and development, production and distribution of
in vitro diagnostics (IVD)**

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 9001

Quality management systems –
Requirements
(ISO 9001:2015)

Valid from	2023-02-19
Valid until	2026-02-18
Registration no.	D1407800012
Report no.	P22-01127-242271
Stuttgart	2023-01-09



Head of Certification Body



Attachment of the certificate

No. D1407800012

date 2023-01-09

Page 1 of 1

Location	Scope
in.vent Diagnostica GmbH Neuendorfstraße 17, 16761 Hennigsdorf	procurement, processing and provision of human biological materials, conducting of diagnostic studies as well as research and development, production and distribution of in vitro diagnostics (IVD)
in.vent Diagnostica GmbH Neuendorfstraße 17a, 16761 Hennigsdorf	procurement, processing and provision of human biological materials, production and distribution of in vitro diagnostics (IVD)
in.vent Diagnostica GmbH Am Postplatz 3a, 16761 Hennigsdorf	processing of human biological materials, conducting of diagnostic studies
in.vent Diagnostica GmbH Horst-Müller-Strasse 9, 16761 Hennigsdorf	processing (storage of human biological raw materials)
in.vent Diagnostika GmbH Veltener Straße 12, 16761 Hennigsdorf	processing (storage of human biological raw materials)





Head of Certification Body