For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

in.vent Diagnostica GmbH
Neuendorfstraße 17
16761 Hennigsdorf
Germany

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 9001

in the scope

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

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 9001:2015 - ISO 9001:2015
Quality management systems – Requirements

Valid from	2024-03-25	Registration No.	D1407800014
Valid until	2026-02-18	Report No.	P23-00389-295737

Stuttgart, 2024-03-25

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

Sites included in the certification:

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

Stuttgart, 2024-03-25

Certification Body

mdc medical device certification GmbH | Kriegerstraße 6 | 70191 Stuttgart | Germany | www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

in.vent DIAGNOSTICA GMBH

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

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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)

medical device certification mdc

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6
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Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de