

Certificate

We hereby certify the company

in.vent Diagnostica GmbH
Neuendorfstraße 17
16761 Hennigsdorf
Germany

in.vent
D I A G N O S T I C A G M B H



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

Quality management system according to EN ISO 13485

in the scope

Development, production and distribution of immunodiagnostic tests (IVD) and conducting clinical trials in connection with IVD, contract development and contract manufacturing of calibration and control materials, reagents and reagent products, and kits for in vitro diagnostics

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

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2026-02-19
Valid until 2029-02-18

Registration No. D1407800017
Report No. P25-00227-325090

Stuttgart, 2026-01-30



mdc
Certification Body



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

Sites included in the certification:

Location	Scope
in.vent Diagnostica GmbH Neuendorfstraße 17, 16761 Hennigsdorf Germany	Development, production and distribution of immunodiagnostic tests (IVD) and conducting clinical trials in connection with IVD, contract development and contract manufacturing of calibration and control materials, reagents and reagent products, and kits for in vitro diagnostics
in.vent Diagnostica GmbH Neuendorfstraße 17a, 16a, 16761 Hennigsdorf Germany	Development, production and distribution of immunodiagnostic tests (IVD) and conducting clinical trials in connection with IVD, contract development and contract manufacturing of calibration and control materials, reagents and reagent products, and kits for in vitro diagnostics
in.vent Diagnostica GmbH Am Postplatz 3a, 16761 Hennigsdorf Germany	Conducting of clinical studies related to IVD
in.vent Diagnostica GmbH Horst-Müller-Straße 9, 16761 Hennigsdorf Germany	Production (storage of calibration and control materials, reagents and reagent products, and kits for in vitro diagnostics)

Stuttgart, 2026-01-30


Certification Body