For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

Mediagnost Gesellschaft für Forschung und Herstellung von Diagnostika GmbH
Aspenhaustraße 25
72770 Reutlingen
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Development, manufacture and distribution of in vitro diagnostic medical devices (immunochemistry and infectious immunology) and their raw materials, as well as the provision of related customer-specific development, production, and logistics services

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	2026-05-21	Registration No.	D1339900007
Valid until	2029-05-20	Report No.	P25-00804-339501

Stuttgart, 2026-05-21

Certification Body

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

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EU Quality Management System Certificate

We hereby certify the company

Mediagnost Gesellschaft für Forschung und Herstellung von Diagnostika GmbH
Aspenhaustraße 25
72770 Reutlingen
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/746 for conformity assessment.

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

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/746.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-05-21	Registration No.	D1339900006
Valid until	2031-05-20	Report No.	P25-00804-339508

Stuttgart, 2026-05-21

Notified Body

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-IVDR-098

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

Devices:

Immunoassay intended to be used to define or monitor physiological status and therapeutic measures

Risk class: B
IVR 0609 Other devices intended to be used to define or monitor physiological status and therapeutic measures

Notes:

For class A devices placed on the market in sterile condition the involvement of mdc is limited to the assessment of the aspects of manufacture concerned with securing and maintaining sterile conditions.

For devices for self-testing and near-patient testing the involvement of mdc additionally refers to the assessment of aspects according to Annex IX, Section 5.1.

For the placing on the market of class D devices an EU technical documentation assessment certificate is also required.

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