

Certificate

Certificate No.: MD 1037243-1-1

Manufacturer: **Bio-Rad Medical Diagnostics GmbH**
Industriestr. 1
63303 Dreieich
Germany

REPs Facility ID: F001100

Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,
PMD Act
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacture and Distribution of in-vitro
diagnostic medical devices used in tissue compatibility testing, blood
grouping and the detection of infectious diseases.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 1150185-130
Issue Date: 2024-02-22
Effective Date: 2024-03-23
Expiry Date: 2027-03-22



Certification officer: M.Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.

Certificate

Certificate No.: MD 1037243-1-1
Manufacturer: **Bio-Rad Medical Diagnostics GmbH**
Industriestr. 1
63303 Dreieich
Germany

The scope of certification includes the following sites:

No.	Location	Scope
/01	Bio-Rad Medical Diagnostics GmbH Industriestr. 1 63303 Dreieich Germany	Design and Development, Production, Preservation, Monitoring and Measurement, Administration REPs Facility ID: F001100
/02	Bio-Rad Medical Diagnostics GmbH Industriestr. 4 63303 Dreieich Germany	Production, Monitoring and Measurement and Preservation REPs Facility ID: F001100
/03	Bio-Rad Medical Diagnostics GmbH Heinrich-Hertz-Str. 1 63303 Dreieich Germany	Packaging, Labelling and Preservation REPs Facility ID: F001100
/04	Bio-Rad Medical Diagnostics GmbH Heinrich-Hertz-Str. 3 63303 Dreieich Germany	Administration and Management REPs Facility ID: F001100

Project No.: 1150185-130
Issue Date: 2024-02-22
Effective Date: 2024-03-23
Expiry Date: 2027-03-22



Certification officer: M.Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.