

Certificate

Certificate No.: MD 3340462-70

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

Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, 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.: 3340462-160

Issue Date: 2021-03-23

Effective Date: 2021-03-23

Expiry Date: 2024-03-22



Certification officer: MSc I. Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9108616772?locale=en
or calling 1-888-743-4652.

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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, Monitoring and Measurement, Management (Quality) REPs Facility ID: F001100
/02	Bio-Rad Medical Diagnostics GmbH Industriestr. 4 63303 Dreieich Germany	Production, Monitoring and Measurement (final product release) and Preservation REPs Facility ID: F001100
/03	Bio-Rad Medical Diagnostics GmbH Heinrich-Hertz-Str. 1 63303 Dreieich Germany	Packaging, Labelling, Preservation (storage/delivery) REPs Facility ID: F001100
/04	Bio-Rad Medical Diagnostics GmbH Heinrich-Hertz-Str. 3 63303 Dreieich Germany	Purchasing, Distribution, Administration and Management (Regulatory Affairs and Managing Director) REPs Facility ID: F001100

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