

Certificate

Quality Management System EN ISO 13485:2016


Registration No.: SX 1037243-1
Certificate Holder: Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Germany

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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1150185-40
Effective date: 2024-06-09
Expiry date: 2027-06-08
Issue date: 2024-03-08
Replaces certificate SX 1037243-1 issued 2021-05-20

This certificate can be validated on <https://www.certipedia.com>


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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Bio-Rad Medical Diagnostics GmbH Industriestr. 1 63303 Dreieich Germany	Design and Development, Manufacture, Preservation, Monitoring and Measurement, Administration
/02	c/o Bio-Rad Medical Diagnostics GmbH Industriestr. 4 63303 Dreieich Germany	Manufacture, Monitoring and Measurement (final product release) and Storage
/03	c/o Bio-Rad Medical Diagnostics GmbH Heinrich-Hertz-Str. 1 63303 Dreieich Germany	Packaging, Labelling, Storage and Distribution
/04	c/o Bio-Rad Medical Diagnostics GmbH Heinrich-Hertz-Str. 3 63303 Dreieich Germany	Purchasing, Distribution and Administration

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