

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 1191616-1

Certificate Holder: IMMUCOR
Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

Scope: Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics.

Manufacture, distribution, installation, servicing, and repair of instrumentation diagnostics.

Distribution of in vitro diagnostic reagents and software for transfusion and transplant diagnostics.

Installation and service of software for transplant diagnostics.

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.: 1184492-100

Effective date: 2025-12-09

Expiry date: 2027-07-22

Issue date: 2025-12-09

Replaces certificate SX 1191616-1 issued 2024-07-19

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 IMMUCOR Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 63303 Dreieich Germany	Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics. Manufacture, distribution, installation, servicing, and repair of instrumentation for transfusion diagnostics. Distribution of in vitro diagnostic reagents and software for transfusion and transplant diagnostics. Installation and service of software for transplant diagnostics.

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