

Certificate

Quality Management System EN 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.: 1155516-20

Effective date: 2024-07-23

Expiry date: 2027-07-22

Issue date: 2024-07-19

Replaces certificate SX 1191616-1 issued 2024-07-11

Irene Carraretto

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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.
/06	c/o Immucor UK (also trading as, Quest Biomedical and IBG Immucor) 2 Cranbook Way Solihull Business Park Solihull B90 4GT United Kingdom	Distribution of in vitro diagnostic reagents and software for transfusion and transplant diagnostics. Distribution, installation, servicing and repair of instrumentation for transfusion diagnostics. Installation, and service of software for transplant diagnostics.

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