

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1191616-1

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

Scope: Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics.
Distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics.
Manufacture, refurbishment, distribution, installation, servicing and repair of instrumentation for transfusion 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.: 1104708-10
Effective date: 2023-03-03
Expiry date: 2024-07-22
Issue date: 2023-03-03



D. Wiedemuth
Dipl.-Ing. (FH) Daniele Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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63303 Dreieich
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o IMMUCOR Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 63303 Dreieich Germany	Design, development, manufacture and distribution of in vitro diagnostic reagents. Manufacture, refurbishment, distribution, installation, servicing and repair of instrumentation.
/02	c/o Immucor S.L. Centre d'Empreses de Noves Tecnologies Parc Tecnològic del Vallès Av. Parc Tecnològic, 3 08290 Cerdanyola del Vallès (Barcelona) Spain	Distribution of in vitro diagnostic reagents. Distribution, installation, servicing and repair of instrumentation.
/03	c/o Immucor France S.A.S. 14 rue Jean-Antoine de Baif 75013 Paris France	Distribution of in vitro diagnostic reagents. Distribution, installation, servicing and repair of instrumentation.

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Germany

The scope of certification also covers the following:

- | | | |
|-----|---|--|
| /04 | c/o Immucor Italia S.p.a.
Via Ettore Bugatti 12
20142 Milano
Italy | Distribution of in vitro diagnostic reagents.
Distribution, installation, servicing and repair
of instrumentation. |
| /05 | c/o Immucor (Portugal) Diagnósticos
Médicos Lda.
TagusPark
Parque de Ciência e Tecnologia
Núcleo Central 333/335
2740-122 Oeiras
Portugal | Distribution of in vitro diagnostic reagents.
Distribution, installation, servicing and repair
of instrumentation. |
| /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.
Distribution, installation, servicing and repair
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