

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**IMMUCOR**  
**Medizinische Diagnostik GmbH**  
**Robert-Bosch-Strasse 32**  
**63303 Dreieich**  
**Deutschland**

has established and applies a quality management system for medical devices  
for the following scope:

**Immucor Europe**

**Scope: see attachment**  
**Additional sites: see attachment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-05-29  
Certificate Registration No.: SX 60139581 0001  
An audit was performed. Report No.: 60239181 001  
This Certificate is valid until: 2021-07-22

Certification Body



Date 2019-05-28



*S. Hoffmann*  
Dipl.-Ing. Sven Hoffmann

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60139581 0001  
**Report No.:** 60239181 001

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

**Scope:**

Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics.  
Distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics.  
Manufacture, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics.

**Certification Body**



**Date:** 2019-05-28

  
**Dipl.-Ing. Sven Hoffmann**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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Certificate**

**Registration No.:** SX 60139581 0001  
**Report No.:** 60239181 001

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

**Scope:**

Additional sites:

Immucor S.L.  
Parc Tecnològic del Vallès  
C/Argenters, 7, Edif.II, Local cB,  
08290 Cerdanyola de Vallès (Barcelona), Spain

Immucor France  
8, rue de la Croix Jarry,  
75013 Paris, France

Immucor Italia S.p.a.  
Via Ettore Bugatti, 12,  
20142 Milano, Italy

Immucor (Portugal) Diagnósticos Médicos Lda.  
TagusPark, Parque de Ciência e Tecnológica, Núcleo Central,  
333/335 2740-0122 Oeiras, Portugal

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

**Scope:**

Additional sites:

Immucor UK  
(also trading as, Quest Biomedical and IBG Immucor)  
2 Cranbrook Way, Solihull Business Park  
Solihull, B90 4GT, United Kingdom

The following activities apply to all additional sites:

Distribution of in vitro diagnostic reagents for  
transfusion and transplant diagnostics.  
Distribution, installation, servicing and repair  
of instrumentation for transfusion diagnostics.

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**Date:** 2019-05-28

  
**Dipl.-Ing. Sven Hoffmann**

