

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha WI 53186
USA

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

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 60139678 0001
An audit was performed. Report No.: 60239244 001
This Certificate is valid until: 2021-01-03

Certification Body



Date 2019-05-29



S. Hoffmann
Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60139678 0001
Report No.: 60239244 001

Organization: Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha WI 53186
USA

Scope: Design, Development and Manufacture of In Vitro Diagnostic Medical Devices, Reagents and Software Used in the Management of Immune Status, Coagulation, Tissue and Immunological Typing. Distribution of In Vitro Diagnostic Analyzers and Reagents.



Date: 2019-05-29

Certification Body




Dipl.-Ing. Sven Hoffmann