

## Certificate

## Quality Management System EN ISO 13485:2016

Registration No.:

SX 1804149-1

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.



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 fulfille

management system is subject to yearly surveillance.

Report No.:

3333169-70

Effective date:

2022-01-04

Expiry date:

2024-01-03

Issue date:

Akkreditierungsstelle D-ZM-14169-01-02

2021-12-13

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

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State of Wisconsin County of Waukesha I certify that this is a true and correct copy of a document in the

possession of Sateesh Kyasaram

Notary and Locken Notary's expiration date: March 28, 2025