

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH • 90431 Nürnberg

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

Contact

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Date December 13, 2021

Application for : QMS

Certificate No. : SX 1804149-1

Requirement : EN ISO 13485:2016

Dear Mrs. Allison Stray,

Your Quality Management System has been audited during the phase 2 on-site audit and fulfills the above-mentioned requirement.

Enclosed please find the new certificate No. SX 1804149-1 with the effective date 2022-01-04 replacing the previous certificate.

Best regards,



Dipl.-Ing. (FH) D. Wiedemuth
Certification body

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

Report No.: 3333169-70
Effective date: 2022-01-04
Expiry date: 2024-01-03
Issue date: 2021-12-13


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