Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1804149-1

Certificate Holder: 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.:
 1147100-10

 Effective date:
 2024-01-04

 Expiry date:
 2027-01-03

 Issue date:
 2023-12-21

Replaces certificate SX 1804149-1 issued 2021-12-13

M.Sc. Irene Carraretto TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com



