

Certificate

Certificate No.: MD 3333169-1011

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

REPs Facility ID: F003971

Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

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.

TÜV Rheinland

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 3333169-160
Issue Date: 2021-12-13
Effective Date: 2022-01-04
Expiry Date: 2024-01-03



Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000009904?locale=en
or calling 1-888-743-4652.