

## Certificate

Certificate No.: Manufacturer: MD 1804149-1-1

Immucor GTI Diagnostics, Inc.

20925 Crossroads Circle Waukesha WI 53186 USA

REPs Facility ID: Certification criteria: F003971

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. 665/2022, RDC ANVISA n. 551/2021, 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.

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.:	1147100-140	
Issue Date:	2023-12-21	
Effective Date:	2024-01-04	
Expiry Date:	2027-01-03	



Certification officer: M.Sc. Irene Carraretto 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.

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