# Certificate

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| Certificate No.: | MD 3333169-70 |
| Manufacturer: | **Immucor GTI Diagnostics, Inc.**<br>20925 Crossroads Circle<br>Waukesha WI 53186<br>USA |
| D-U-N-S No.: | 60-603-4197 |
| Certification criteria: | ISO 13485:2016<br>Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure<br>Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009<br>Canada Medical Devices Regulations – Part 1 – SOR 98/282<br>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).

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| Project No.: | 3333169-70 |
| Issue Date: | 2020-12-22 |
| Effective Date: | 2021-01-04 |
| Expiry Date: | 2022-01-03 |

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: MSc 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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