

Certificate

Certificate No.: MD 1804147-1-1

Manufacturer: **Immucor, Inc.**
3130 Gateway Drive
Norcross GA 30071
USA

REPs Facility ID: F003968

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. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Scope: Design and development, manufacture and distribution of In Vitro diagnostics devices, instrumentation and biological products for blood bank and clinical laboratory applications. Installation and servicing of instrumentation for blood bank and clinical laboratory applications.

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.: 1137412-230

Issue Date: 2023-11-30

Effective Date: 2024-02-29

Expiry Date: 2027-02-28



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/9000010017?locale=en or calling 1-888-743-4652.

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The scope of certification includes the following additional sites:

No.	Location	Scope
/01	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA	Manufacture REPs Facility ID: F003968
/02	Immucor, Inc. 7000 Gateway Drive Norcross GA 30071 USA	Design and development REPs Facility ID: F003968
/03	Immucor, Inc. 3150 Gateway Drive Norcross GA 30071 USA	Management (regulatory affairs) REPs Facility ID: F003968
/04	Immucor, Inc. Suite 400 2990 Gateway Drive Norcross GA 30071 USA	Manufacture REPs Facility ID: F003968

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Irene Carraretto

Certification officer: M.Sc. Irene Carraretto
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The scope of certification includes the following additional sites:

- | | | |
|-----|--|--|
| /05 | Immucor, Inc.
2985 Gateway Drive
Norcross GA 30071
USA | Distribution, installation, monitoring and measurement

REPs Facility ID: F003968 |
| /06 | Immucor, Inc.
Suite 150
2975 Gateway Drive
Norcross GA 30071
USA | Management (regulatory affairs)

REPs Facility ID: F003968 |
| /07 | Immucor, Inc.
2935 Gateway Drive
Norcross GA 30071
USA | Distribution, purchasing, servicing, monitoring and measurement

REPs Facility ID: F003968 |
| /08 | Immucor, Inc.
Suite 900
2990 Gateway Drive
Norcross GA 30071
USA | Monitoring and measurement

REPs Facility ID: F003968 |
| /09 | Immucor, Inc.
Suite 200
2975 Gateway Drive
Norcross GA 30071
USA | Management (regulatory affairs)

REPs Facility ID: F003968 |

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