

Certificate

Certificate No.: MD 3330961-160

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

D-U-N-S No.: 06-144-6282

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

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.: 3330961-160

Issue Date: 2020-12-14

Effective Date: 2020-12-14

Expiry Date: 2022-02-28



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 sites:

No.	Location	Scope
/01	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA	Manufacture
/02	Immucor, Inc. 7000 Gateway Drive Norcross GA 30071 USA	Design and Development
/03	Immucor, Inc. 3150 Gateway Drive Norcross GA 30071 USA	Management (regulatory affairs)
/04	Immucor, Inc. Suite 400 2990 Gateway Drive Norcross GA 30071 USA	Manufacture
/05	Immucor, Inc. 2985 Gateway Drive Norcross GA 30071 USA	Distribution, installation, monitoring and measurement

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- | | | |
|-----|--|--|
| /06 | Immucor, Inc.
Suite 150
2975 Gateway Drive
Norcross GA 30071
USA | Management (regulatory affairs) |
| /07 | Immucor, Inc.
2935 Gateway Drive
Norcross GA 30071
USA | Distribution, purchasing, servicing,
monitoring and measurement |
| /08 | Immucor, Inc.
Suite 900
2990 Gateway Drive
Norcross GA 30071
USA | Monitoring and measurement |
| /09 | Immucor, Inc.
Suite 200
2975 Gateway Drive
Norcross GA 30071
USA | Management (regulatory affairs) |

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