Certificate

TÜVRheinland®

Certificate No.:	MD 1804147 3287506-130
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 (as applicable) United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and manufacture of In Vitro diagnostics devices and biological products for blood bank and clinical laboratory applications. Design, manufacture 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.:	60238843-001
Issue Date:	2019-05-29
Effective Date:	2019-05-29
Expiry Date:	2021-02-28

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

H. Lüdemann

Certification officer: Dr. H. Lüdemann
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on www.certipedia.com, via the QR code or calling 1-888-743-4652.

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