

Certificate

Quality Management System EN ISO 13485:2016


Registration No.: SX 1804147-1
Certificate Holder: Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Scope: Design, development and manufacture of in vitro diagnostic devices and biological products for blood bank and clinical laboratory applications.
Design, development, manufacture, installation and service of instrumentation for blood bank and clinical laboratory applications.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1137412-40
Effective date: 2024-02-29
Expiry date: 2027-02-28
Issue date: 2023-11-30
Replaces certificate SX 1804147-1 issued 2021-03-01

This certificate can be validated on <https://www.certipedia.com>


M.Sc. Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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USA

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA	Manufacture
/02	c/o Immucor, Inc. 7000 Gateway Drive Norcross GA 30071 USA	Design and development
/03	c/o Immucor, Inc. 3150 Gateway Drive Norcross GA 30071 USA	Administration
/04	c/o Immucor, Inc. Suite 400 2990 Gateway Drive Norcross GA 30071 USA	Manufacture
/05	c/o Immucor, Inc. 2985 Gateway Drive Norcross GA 30071 USA	Distribution, installation and administration

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USA

The scope of certification also covers the following sites:

- | | | |
|-----|---|--|
| /06 | c/o Immucor, Inc.
Suite 150
2975 Gateway Drive
Norcross GA 30071
USA | Administration |
| /07 | c/o Immucor, Inc.
2935 Gateway Drive
Norcross GA 30071
USA | Distribution, service and administration |
| /08 | c/o Immucor, Inc.
Suite 900
2990 Gateway Drive
Norcross GA 30071
USA | Manufacture and quality control |
| /09 | c/o Immucor, Inc.
Suite 200
2975 Gateway
Drive
Norcross GA 30071
USA | Administration |

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