

# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1804147-1

Organization: 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.: 3330961-70  
Effective date: 2021-03-01  
Expiry date: 2024-02-28  
Issue date: 2021-03-01



Dipl.-Ing. Sven Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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3130 Gateway Drive  
Norcross GA 30071  
USA

The scope of certification also covers the following:

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

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3130 Gateway Drive  
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USA

The scope of certification also covers the following:

- |     |  |   |
|-----|--|---|
| /05 | c/o Immucor, Inc.<br>2985 Gateway Drive<br>Norcross GA 30071<br>USA              | Distribution, installation and administration |
| /06 | c/o Immucor, Inc.<br>Suite 150<br>2975 Gateway Drive<br>Norcross GA 30071<br>USA | Administration                                |
| /07 | c/o Immucor, Inc.<br>2935 Gateway Drive<br>Norcross GA 30071<br>USA              | Distribution, service and administration      |
| /08 | c/o Immucor, Inc.<br>Suite 900<br>2990 Gateway Drive<br>Norcross GA 30071<br>USA | Manufacture and quality control               |

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USA

The scope of certification also covers the following:

/09 c/o Immucor, Inc. Administration  
Suite 200  
2975 Gateway Drive  
Norcross GA 30071  
USA

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