

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

i-Sep
21 rue de la Noue Bras de Fer
Nantes
44200
France

Holds Certificate Number:

MD 687308

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and manufacture of blood auto transfusion device, sterile disposable sets and sterile and non-sterile disposable consumables for use with the auto transfusion device.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-01-17

Latest Revision Date: 2020-01-17

Effective Date: 2020-01-17

Expiry Date: 2023-01-16

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