

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

COOK BioDevice
500 W. Simpson Chapel Road
Bloomington
Indiana
47404
USA

Holds Certificate No:

FM 702429

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

Design, development, manufacture, and distribution of sterile and non-sterile medical devices for use in collection, separation, and delivery of therapeutic cellular, blood, and tissue products, including wire guides, needles, catheters, and separation systems.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-02-16

Latest Revision Date: 2019-06-20

Effective Date: 2019-02-16

Expiry Date: 2022-02-15

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