

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

DUNS Number: 08-041-1091

Holds Certificate No:

MDSAP 693555

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-04-16

Effective Date: 2020-04-16

Expiry Date: 2023-02-15



BSI Group America Inc. is an MDSAP authorized auditing organization

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