

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette
Indiana
47906
USA

Facility ID Number: F005325

Holds Certificate No: **MDSAP 743355**

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; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 821

Design and Development, Production and Distribution of Porcine Wound Dressings and Porcine Soft Tissue Grafts, and Enterocutaneous Fistula Plug Delivery System.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-07-20

Effective Date: 2022-02-02

Expiry Date: 2024-02-22



BSI Group America Inc. is an MDSAP authorized auditing organization

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