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America

CERTIFICATE

No. QS6 18 02 39164 113

Certificate Holder: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette IN 47906
USA

Certification Mark:

Scope of Certificate: Design, Development, Manufacture, and Distribution of Porcine Wound Dressings and Porcine Soft Tissue Grafts, and Enterocutaneous Plug Delivery System, Cells, Blood, Blood Components and Tissue Storage Containers

Standard(s): ISO 13485:2016

Regulatory Authority: TGA, ANVISA, Health Canada, FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Authorized Auditing Organization.

DUNS No: 94-538-5862
Effective Date: 2018-02-23
Expiry Date: 2021-02-22

Manuel Bradaric
MHS Certification Manager

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America

CERTIFICATE

No. QS6 18 02 39164 113

Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1
- Schedule 3, Part 4

Brazil

- Federal Law n. 6360/76
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009
- RDC ANVISA n. 56/2001

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Japan

- MHLW Ministerial Ordinance No.169, 2004

Effective Date: 2018-02-23
Expiry Date: 2021-02-22

Manuel Bradaric
Certification Manager MHS

TÜV SÜD AMERICA INC • 10 Centennial Drive • Peabody, MA 01960 USA • www.TUVamerica.com

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