



America

CERTIFICATE

No. QS6 039164 0121 Rev. 00

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(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA 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 www.tuvsud.com/ps-cert
 TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **94-538-5862**

Effective Date: **2021-03-12**

Expiry Date: **2022-02-22**

Page 1 of 2

Date of Issue: 2021-03-12

(Tina Israel)
 Manager, US Certification Body,
 Medical and Health Services



America

CERTIFICATE

No. QS6 039164 0121 Rev. 00

Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

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

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820
 - 21 CFR Part 821

Facility(ies):

Cook Biotech Incorporated
 1425 Innovation Place, West Lafayette IN 47906, USA

Facility Scopes:

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
 DUNS No: 94-538-5862

Page 2 of 2

Date of Issue: 2021-03-12

(Tina Israel)
 Manager, US Certification Body,
 Medical and Health Services