ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 11 39164 091

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

EC-Representative:
Cook Ireland Limited
O'Halloran Road
National Technology Park
Limerick
IRELAND

Product Category(ies):
Porcine Wound Dressing and Porcine Soft Tissue Graft, and Enterocutaneous Fistula Plug Delivery System, and Storage Containers for Cells, Tissue, Blood, and Blood Components

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: NM1203448

Valid from: 2015-03-21
Valid until: 2020-03-20

Date, 2015-03-17

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

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ZAS / 09.10

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