

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 743262
Issued To: **Cook Biotech Incorporated**
1425 Innovation Place
West Lafayette
Indiana
47906
USA

In respect of:

The design, development, and manufacture of sterile porcine wound dressings and sterile porcine soft tissue grafts.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-05-17**

Date: **2021-05-17**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 743262

Issued To:

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette
Indiana
47906
USA

Device Code	Device Name	Intended purpose per IFU
Class III		
---	AxoGuard® Nerve Protector AxoGuard® Nerve Connector	See CE 743215
	Biodesign® 4-Layer Tissue Graft	See CE 743216
	Biodesign® Dural Graft Biodesign® Duraplasty Graft	See CE 743217
	Biodesign® Fistula Plug	See CE 743218
	Biodesign® Hernia Graft	See CE 743219
	Biodesign® Hiatal Hernia Graft	See CE 743220
	Biodesign® Otologic Repair Graft	See CE 743222
	Biodesign® Rectopexy Graft	See CE 743223
	Oasis® Extracellular Matrix	See CE 743224

First Issued: **2021-05-17**

Date: **2021-05-17**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 743262**
Date: **2021-05-17**
Issued To: **Cook Biotech Incorporated**
1425 Innovation Place
West Lafayette
Indiana
47906
USA

Subcontractor:	Service(s) supplied
Banner Creek 619 E 4th Street Holton Kansas 66436 USA	Crucial Supplier
Cook Biotech Europe ApS Sandet 6, DK-4632 Bjaeverskov Denmark	EU Representative
Cook Incorporated-Ellettsville North 6300 North Matthews Drive Ellettsville Indiana 47429 USA	ETO Sterilization

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

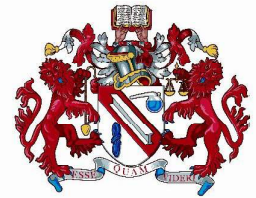
List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 743262**
Date: **2021-05-17**
Issued To: **Cook Biotech Incorporated**
1425 Innovation Place
West Lafayette
Indiana
47906
USA

Subcontractor:	Service(s) supplied
Momence Packing 334 West North Street Momence Illinois 60954 USA	Crucial Supplier
Pine Ridge Farms 1800 Maury Street Des Moines Iowa 50317 USA	Crucial Supplier

...making excellence a habit.™



EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 743262**
Date: **2021-05-17**
Issued To: **Cook Biotech Incorporated**
1425 Innovation Place
West Lafayette
Indiana
47906
USA

Date	Reference Number	Action
Current	3372380	First issue, transfer from another Notified Body.

