By Royal Charter

EC Design-Examination Certificate

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

No. **CE 743215**

Issued To: **Cook Biotech Incorporated**
1425 Innovation Place
West Lafayette
Indiana
47906
USA

In respect of:

AxoGuard® Nerve Protector
AxoGuard® Nerve Connector

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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**

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EC Design-Examination Certificate

Supplementary Information to CE 743215

Issued To:

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette
Indiana
47906
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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
AG0220-2	AxoGuard® Nerve Protector	Diam: 2mm Length: 20 mm	The Axoguard Nerve Protector is indicated for the repair of peripheral nerve injuries where there is no gap.	Class III, implantable
AG0320-2	AxoGuard® Nerve Protector	Diam: 3.5 mm Length: 20 mm		
AG0340-2	AxoGuard® Nerve Protector	Diam: 3.5 mm Length: 40 mm		
AG0520-2	AxoGuard® Nerve Protector	Diam: 5 mm Length: 20 mm		
AG0540-2	AxoGuard® Nerve Protector	Diam: 5 mm Length: 40 mm		
AG0720-2	AxoGuard® Nerve Protector	Diam: 7 mm Length: 20 mm		
AG0740-2	AxoGuard® Nerve Protector	Diam: 7 mm Length: 40 mm		
AG1020-2	AxoGuard® Nerve Protector	Diam: 10 mm Length: 20 mm		
AG1040-2	AxoGuard® Nerve Protector	Diam: 10 mm Length: 40 mm		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
AGX110-2	AxoGuard® Nerve Connector	Diam: 1.5 mm Length: 10 mm	The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm.	Class III, implantable
AGX115-2	AxoGuard® Nerve Connector	Diam: 1.5 mm Length: 15 mm		
AGX210-2	AxoGuard® Nerve Connector	Diam: 2 mm Length: 10 mm		
AGX215-2	AxoGuard® Nerve Connector	Diam: 2 mm Length: 15 mm		
AGX310-2	AxoGuard® Nerve Connector	Diam: 3 mm Length: 10 mm		
AGX315-2	AxoGuard® Nerve Connector	Diam: 3 mm Length: 20 mm		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
AGX410-2	AxoGuard® Nerve Connector	Diam: 14 mm Length: 10 mm	The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm.	Class III, implantable
AGX415-2	AxoGuard® Nerve Connector	Diam: 4 mm Length: 15 mm		
AGX510-2	AxoGuard® Nerve Connector	Diam: 5 mm Length: 10 mm		
AGX515-2	AxoGuard® Nerve Connector	Diam: 5 mm Length: 15 mm		
AGX610-2	AxoGuard® Nerve Connector	Diam: 6 mm Length: 10 mm		
AGX710-2	AxoGuard® Nerve Connector	Diam: 7 mm Length: 10 mm		

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1425 Innovation Place
West Lafayette
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Certificate History

Date	Reference Number	Action
Current	3372365	First issue, transfer from another Notified Body

First Issued: **2021-05-17** Date: **2021-05-17** Expiry Date: **2024-05-26**

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COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

MANUFACTURER SELF-DECLARATION

Under the following conditions, Cook Biotech Incorporated certify that the devices covered by this declaration are compliant with Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as to the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices.

a) All devices listed on Appendix 1 of this declaration continue to comply with Directive 93/42/EEC;
b) There are no significant changes in the design and intended purpose of the products since the certificate has been issued;
c) The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
d) Cook Biotech Incorporated Quality Management System has been audited for compliance with Regulation (EU) 2017/745 on January 10-12, 2023, by BSI;
e) Cook Biotech Incorporated have signed a written agreement with BSI in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745

Pursuant to the terms of Regulation (EU) 2023/607, the devices listed in this self-declaration shall remain covered by the CE mark until December 31, 2027.

Sincerely yours,

Michael C Hiles, PHD
Senior VP R&D and CSO
Cook Biotech Incorporated

02May23
Date

Cut Bogue
Director of Quality Assurance
Cook Biotech Incorporated

02May2023
Date

Appendix 1_CE-MARKED PRODUCT LISTING_COOK BIOTECH

Product name	All article/model numbers	Classification MDD (EU) 2017/745	EC Design Certificate	EC Valid MDD (EU) 2017/745	EC Valid MDR (EU) 2023/607
AxoGuard Nerve Protector /Connector	AGX110-2 AGX115-2 AGX210-2 AGX215-2 AGX310-2 AGX315-2 AGX410-2 AGX415-2 AGX510-2 AGX515-2 AGX610-2 AGX710-2 AG0220-2 AG0320-2 AG0340-2 AG0520-2 AG0540-2 AG0720-2 AG0740-2 AG1020-2 AG1040-2	III	CE 743215	26-May-24	31-Dec-2027
Biodesign® 4-Layer Tissue Graft	SLH-4S-2X3-2 SLH-4S-3.5X5-2 SLH-4S-4X7-2 SLH-4S-7X10-2 SLH-4S-7X20-2	III	CE 743216	26-May-24	31-Dec-2027
Biodesign® Dural Graft	C-DUR-2X3-2 C-DUR-4X7-2 C-DUR-7X10-2 C-DUR-7X20-2	III	CE 743217	12-May-23	31-Dec-2027
Biodesign® Duraplasty Graft	ENT-CBD-1X2-2 ENT-CBD-2.5X2.5-2 ENT-CBD-5X5-2 ENT-CBD-7X8.5-2	III	CE 743217	12-May-23	31-Dec-2027
Biodesign® Fistula Plug	C-FP-0.2-2 C-FP-0.4-2 C-FP-0.7-2	III	CE 743218	26-May-24	31-Dec-2027
Biodesign® Hernia Graft	C-SLH-8H-10X10-2 C-SLH-8H-13X15-2 C-SLH-8H-13X22-2 C-SLH-8H-20X20-2 C-SLH-8H-20X30-2	III	CE 743219	27-Sep-23	31-Dec-2027
Biodesign® Hiatal Hernia Graft	C-PHR-7X10-2 C-PHR-7X10-U-2	III	CE 743220	26-May-24	31-Dec-2027
Biodesign® Otologic Repair Graft	ENT-OTO-0.4-0.6-2 ENT-OTO-0.6-0.9-2 ENT-OTO-2.5X2.5-2 ENT-OTO-5X5-2	III	CE 743222	26-May-24	31-Dec-2027
Biodesign® Rectopexy Graft	C-BRG-7X20-2	III	CE 743223	26-May-24	31-Dec-2027
Oasis® Extracellular Matrix	C-ECM-1F-3X3.5-2 C-ECM-1F-3X7-2 C-ECM-1F-3X3.5-1-2 C-ECM-1F-3X3.5-2-2 C-ECM-1F-3X7-1-2 C-ECM-1M-7X10-2 C-ECM-1M-7X20-2 C-ECM-2M-7X20-2	III	CE 743224	26-May-24	31-Dec-2027

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette
Indiana
47906
USA

08 November 2023

Notified Body Confirmation Letter
Reference: EU2023-607/723730

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette
Indiana
47906
USA

SRN Number: US-MF-000001990

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the

corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Biodesign® Hernia Graft	Class III	Not Applicable	CE 743219, CE 743262 NB 2797
AxoGuard Nerve Protector /Connector	Class III	Not Applicable	CE 743215, CE 743262 NB 2797
Biodesign® Dural Graft/Duraplasty Graft	Class III	Not Applicable	CE 743217, CE 743262 NB 2797
Biodesign® Rectopexy Graft	Class III	Not Applicable	CE 743223, CE 743262 NB 2797
Oasis® Extracellular Matrix	Class III	Not Applicable	CE 743224, CE 743262 NB 2797
Biodesign® Otologic Repair Graft	Class III	Not Applicable	CE 743222, CE 743262 NB 2797
Biodesign® Fistula Plug	Class III	Not Applicable	CE 743218, CE 743262 NB 2797
Biodesign® Hiatal Hernia Graft	Class III	Not Applicable	CE 743220, CE 743262 NB 2797
Biodesign® 4-Layer Tissue Graft	Class III	Not Applicable	CE 743216, CE 743262 NB 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	Choose an item.	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/11/08	Initial issue