



# 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<sup>®</sup> Nerve Protector  
AxoGuard<sup>®</sup> 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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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 certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 743215

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