EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 771070 R000

Manufacturer: Cook Biotech Incorporated

Address:
1425 Innovation Place
West Lafayette
Indiana
47906
USA

Single Registration Number: US-MF-000001990

EU Authorised Representative: Cook Biotech Europe ApS

Address:
Sandet 6, DK-4632
Bjaeverskov
Denmark

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-09-23**

Current Issue Date: **2025-09-23**

Starting Validity Date: **2025-09-23**

Expiry Date: **2030-09-22**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 771070 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Axoguard® Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm. The Axoguard® Nerve Connector is supplied sterile and is intended for single use.

The Axoguard® Nerve Protector is indicated for the repair of peripheral nerve injuries where there is no gap. The Axoguard® Nerve Protector is supplied sterile and is intended for single use.

Type (Codes as per (EU) 2017/2185): MDN1104

Risk Classification: Class III Implantable

Basic UDI-DI: 0827002AXOGUARDXB

Device Name	Model	Description	
		Diameter (mm)	Length (cm)
Axoguard® Nerve Connector	AGX110-2	1.5	10
	AGX115-2	1.5	15
	AGX210-2	2	10
	AGX215-2	2	15
	AGX310-2	3	10
	AGX315-2	3	15
	AGX410-2	4	10
	AGX415-2	4	15
	AGX510-2	5	10
	AGX515-2	5	15
	AGX610-2	6	10
	AGX710-2	7	10

First Issue Date: **2025-09-23**

Current Issue Date: **2025-09-23**

Starting Validity Date: **2025-09-23**

Expiry Date: **2030-09-22**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 771070 R000

Device Name	Model	Description	
		Diameter (mm)	Length (cm)
Axoguard® Nerve Protector	AG0220-2	2	20
	AG0320-2	3.5	20
	AG0340-2	3.5	40
	AG0520-2	5	20
	AG0540-2	5	40
	AG0720-2	7	20
	AG0740-2	7	40
	AG01020-2	10	20
	AG01040-2	10	40

First Issue Date: **2025-09-23**

Current Issue Date: **2025-09-23**

Starting Validity Date: **2025-09-23**

Expiry Date: **2030-09-22**

...making excellence a habit.™

By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 771070 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3679050	Issued

First Issue Date: **2025-09-23**

Current Issue Date: **2025-09-23**

Starting Validity Date: **2025-09-23**

Expiry Date: **2030-09-22**

...making excellence a habit.™