



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

DECLARATION OF CONFORMITY

Axoguard® Nerve Connector Axoguard® Nerve Protector

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

EU Representative: Cook Biotech Europe ApS
Sandet 6, DK-4632
Bjaeverskov, Denmark

Product: Axoguard® Nerve Connector
Axoguard® Nerve Protector
(See RPNs in attached Schedule)

CE Conformity Assessment Procedure: Annex II, Item 4

Classification: Class III, Rules 8 & 17, According to Annex IX of the MDD

We declare under sole responsibility that the above-named product meets the provisions of the Council Directive 93/42/EEC for medical devices. Cook Biotech Incorporated retains all supporting data at the West Lafayette premises.

Standards Applied BS EN 556-1:2001/AC:2006; BS EN 1041:2008+A1:2013; ISO 10993-1:2020; BS EN ISO 10993-2:2006; BS EN ISO 10993-3:2014; BS EN ISO 10993-5:2009; BS EN ISO 10993-6:2016; BS EN ISO 10993-7:2008/Amd1:2019; ISO 10993-9:2019; BS EN ISO 10993-10:2013; BS EN ISO 10993-11:2018; BS EN ISO 10993-12:2012; BS EN ISO 10993-18:2020; ISO 11135:2014/Amd.1:2018; ISO 11607-1:2019; BS EN ISO 11607-2:2020; BS EN ISO 11737-1:2018; BS EN ISO 13485:2016/AC:2016; BS EN ISO 14155:2020; BS EN ISO 14630:2012, BS EN ISO 14644-1:2015; ISO 14644-2:2015; BS EN ISO 14971:2012; BS EN ISO 15223-1:2016+Corr. 2017; BS EN ISO 22442-1,-2:2020; BS EN ISO 22442-3:2007; ASTM F1886/F1886M-16.

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam-Netherlands
Identification Number 2797

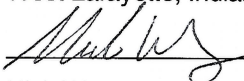
Start of CE-Marking: 25 April 2013

EC Certificate, Full Quality System: CE 743262

EC Design Examination Certificate: CE 743215

Place of Issue: West Lafayette, Indiana, USA

Signature:

 Date: 21 May 2021

Nick Wang

Director of Regulatory Affairs



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See attached Declaration of Conformity
Schedule of RPNs

Axoguard® Nerve 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

Axoguard® Nerve Protector

AG0220-2
AG0320-2
AG0340-2
AG0520-2
AG0540-2
AG0720-2
AG0740-2
AG1020-2
AG1040-2