



Product Service

# EC Certificate

## EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

No. G7 13 06 39164 084

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

**EC-Representative:** **Cook Ireland Limited**  
O'Halloran Road  
National Technology Park  
Limerick  
IRELAND

**Product:** **Collagen Implants**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

**Report no.:** 713025343

**Valid from:** 2013-07-15

**Valid until:** 2018-04-24

**Date,** 2013-07-16

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**Model(s):** Porcine Soft Tissue Grafts**Parameters:**

AxoGuard Nerve Protector		
	Diameter (cm)	Length (cm)
AG0220	0.2	2.0
AG0320	0.35	2.0
AG0520	0.5	2.0
AG0720	0.7	2.0
AG1020	1.0	2.0
AG0340	0.35	4.0
AG0540	0.5	4.0
AG0740	0.7	4.0
AG1040	1.0	4.0

AxoGuard Nerve Connector		
	Diameter (cm)	Length (cm)
AGX110	0.15	1.0
AGX210	0.2	1.0
AGX310	0.3	1.0
AGX410	0.4	1.0
AGX510	0.5	1.0
AGX610	0.6	1.0
AGX710	0.7	1.0
AGX115	0.15	1.5
AGX215	0.2	1.5
AGX315	0.3	1.5
AGX415	0.4	1.5
AGX515	0.5	1.5
AGX615	0.6	1.5
AGX715	0.7	1.5