EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 757757 R000

Manufacturer: Phagenesis Ltd

Address:
Unit 18 Enterprise House
Manchester Science Park
Manchester
M15 6SE
United Kingdom

Single Registration Number: GB-MF-000015848

EU Authorised Representative: Medidee Services (Deutschland) GmbH

Address:
Hohnenweg 9
78098 Triberg im Schwarzwald
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II 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 Medical Devices

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Neurological stimulators	Class IIa
Sterile Catheter	Class IIa

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