EU Declaration of Conformity

Identification of the Legal Manufacturer	Phagenesis Ltd.
Manufacturer Address	Unit 18 Enterprise house, Manchester Science Park, Manchester, M15 6SE, United Kingdom.
Manufacturer SRN	GB-MF-000015848
Identification of Authorized Representative	Veranex Germany GmbH, Landsberger Strasse 302, 80687 Munich, Germany.
Authorized Representative SRN	DE-AR-000005578
This Declaration of Conformity is issued under the sole responsibility of the above mentioned Legal Manufacturer	
Basic UDI-DI	506045348C019T
Name of the Device	Phagenyx PNX-1000 Catheter
Phagenesis Catalogue reference	PNX-1000
Intended purpose	The intended use of the Phagenyx System is to restore swallow function using neurostimulation and to provide nutritional support for patients who require liquid feedings as a substitute for solid food.
Risk Classification	IIa (Rule 5 as per Annex XIII of 2017/745)
We hereby declare that the above mentioned device(s) meet the provision of the Regulation EU 2017/745 MDR for medical devices and is CE marked in accordance with Annex IX. This declaration is supported by the Quality System approval to ISO 13485 issued by BSI. All supporting documentation is retained at the premise of the manufacturer.	
Name and address of Notified Body	BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. Netherlands
Notified Body N° / Applicable CE certificate(s)	2797 / MDR757757
Validity of the Declaration of Conformity	From 08 July 2022 Until 07 July 2027
Identification of the person authorized to sign on behalf of Legal Manufacturer: Phagenesis Limited Unit 18 Enterprise House Manchester Science Park Manchester, M15 6SE Reg No. 06308699 PHAGENESIS®	Name Conor Mulrooney Signature Title COO Place of Issue Manchester Date of Issue 01 August 2024