# EU Declaration of Conformity

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| 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 | 506045348B039S |
| Name of the Device | Phagenyx EPSB3 Base Station |
| Phagenesis Catalogue reference | EPSB3 |
| 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 9 as per Annex VIII 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.<br>This declaration is supported by the Quality System approval to ISO 13485 issued by BSI.<br>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<br>Until 07 July 2027 |
| Identification of the person authorized to sign on behalf of Legal Manufacturer:<br>Phagenesis Limited<br>Unit 18 Enterprise House<br>Manchester Science Park<br>Manchester, M15 6SE<br>Reg No. 06308699<br>PHAGENESIS® | Name Conor Mulrooney<br>Signature<br>Title COO<br>Place of Issue Manchester<br>Date of Issue 01 August 2024 |