Declaration de conformity (EU)

We,
ORTHOPUS
SRN : FR-MF-000037107
Le Karting - Bloc 3
6 rue Saint Domingue
44 200 Nantes
FRANCE ,

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

The ORTHOPUS Supporter (OR - 0204), and its accessories,

having the intended purpose : Orthopus Supporter is a dynamic arm support. It is designed for individuals who require significant compensation against gravity to perform human arm movements.

The company ORTHOPUS hereby guarantees and declares, in accordance with Article 19 of Regulation (EU) 2017/745, that the following medical device:

Photo	Product Name	Basic UDI-DI	Device Class	Nomencla-ture EMDN	ISO 9999 Classification	Version
	ORTHOPUS Supporter	377002647802 04NX	Class I	Y241899 Assistive and/or substitute devices for arm, hand, finger - Other	Robotic manipulators (24.18.30)	Product V.1.1 Software V.1.0.6

Is in conformity with the applicable requirements and provisions of:

- Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002, and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC;
- and the French Public Health Code.

This declaration is based on the following elements:

- Technical Documentation: OR-0204, which demonstrates the conformity of our device with the general safety and performance requirements in accordance with Annex II, Annex III of Regulation (EU) 2017/745, and Articles R.5211-21 to R.5211-23 of the French Public Health Code;
- Device Classification: The class of our medical device is determined in accordance with Rule 13 of Annex VIII "Classification Rules" of Regulation (EU) 2017/745.

Date: 2024/08/19
Nom, position and signature:
David Gouaillier, CEO

Company Seal:

ORTHOPUS
Le Karting
6 rue Saint Domingue 44 200 Nantes
SAS au capital social de 106 718€
SIREN : 843 788 811 - **SIRET** : 84378881100027
NAF / APE : 4646Z
TVA : FR28843788811
Inscrit au RCS de Nantes : 843 788 811