

**EU DECLARATION OF CONFORMITY OF MEDICAL DEVICE
DRAWN UP BY THE MANUFACTURER**

Manufacturer: Pro Medicare S.r.l. with registered office and operational headquarters
in Mesagne (BR) Via Montagna

General Device Name: "Helix Postural system with related accessories"

UDI-DI BASIC: 805571347HELIXD2

SRN: IT-MF-000022537

Devices Codes:

D00-001-1 "HELIX Total-Body Pronation Positioning Device"

D00-002-1 "Head-kit positioning device"

Pursuant to Article 19 of the EU Regulation 2017/745 of the European Parliament and Council, the undersigned, Dr. Franco Cariolo, Sole Director and Legal Representative of Pro Medicare S.r.l., manufacturer of standard class I medical devices according to the rules provided, having performed the conformity assessment as prescribed by the above Regulation and having fully complied with the procedures established in Chapter V Section 2 and Annex II and III,

ensures and declares that

- the devices comply with the requirements set out in article 5 and in Annex I, therefore can be lawfully placed on the market and into service after affixing the CE Mark as required in Article 20 of the EU Regulation 2017/745.
- Pro Medicare S.r.l. is responsible for the design, manufacture, packaging, and labeling.

Mesagne (BR), 30/04/2024

Pro Medicare S.r.l.
Sole Director and Legal Representative
L'amministratore Unico