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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: "*Positioning Device AUXIFORM*"

UDI-DI BASIC: 805571347SOLLIEVOE8

SRN: IT-MF-000022537

Device Code:

Inflect model: D00-027-1/2/3/4

Contens model: D00-028-1/2/3/4

Imples model: D00-029-1/2/3

Articula high 6 model: D00-037-0/1/2/3

Articula high 8 model: D00-034-0/1/2/3

Articula high 11 model: D00-030-0/1/2/3

Articula high 15 model: D00-031-0/1/2/3

Articula high 14 model: D00-032-1/2/3/4

Articula high 18 model: D00-033-1/2/3/4

Articula Reverso A model: D00-035-1; Articula Reverso B model: D00-036-1

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), 28/03/2023

Pro Medicare S.r.l.
Sole Administrator
L'amministratore Unico