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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: "Modular Cushion PROX"

UDI-DI BASIC: 805571347SOLLIEVOE8

SRN: available after EUDAMED implementation

Device Codes: ***D00-008-1***

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), 02/05/2022

Pro Medicare S.r.l.

Sole Director and Legal Representative

L'Amministratore Unico