

**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: "Startis line posture system with related accessories"

UDI-DI BASIC: 805571347STARTISZH

Manufacturers SRN: IT-MF-000022537

Device Code: As per Appendix "All.Dic.Con.Sta. EN 1 10/03/2025"

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), 10/03/2025

Pro Medicare S.r.l.
Sole Director and Legal Representative


L'amministratore Unico



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Annex to the Declaration of
Conformity

All.Dic.Con.Sta. EN
Rev.1 10/03/2025

Range Code - Description of the Device

STARTIS	D03-(X)01-1 - Whippy Positioning System
	<u>TECHNICAL FEATURES:</u> D03: Startis Range X: color COLOR: 2: pastel green; 5: sage green
STARTIS	S03-(X)0001-1 - Flexible leg extension kit with positioners
	<u>TECHNICAL FEATURES:</u> S03: Startis Range accessory X: color COLOR: 2: pastel green; 5: sage green
STARTIS	S03-(X)0002-1 - Pelvic belt
	<u>TECHNICAL FEATURES:</u> S03: Startis Range accessory X: color COLOR: 2: pastel green; 5: sage green
STARTIS	D03-202-X - Bibi Total Body Positioning Kit
	<u>TECHNICAL FEATURES:</u> D03: Startis Range X: size SIZES: 1: size 1; 2: size 2