

**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: " Head Support and containment systems in lying
and reclining position"

UDI-DI BASIC: 805571347SOLLIEVOE8

Manufacturers SRN: IT-MF-000022537

Device Code: As per Appendix "All.Dic.Con.Sis.Sos.Con.Cap. EN Rev.0 09/05/2024"

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), 09/05/2024

Pro Medicare S.r.l.

Sole Director and Legal Representative

Pro Medicare
SRL
L'Amministratore Unico

Pro Medicare s.r.l.

C.F. e P. Iva 01803920741 - Cap. Soc. € 10.000,00 (i.v.) - C.C.I.A.A. n° 102141 - Reg. Trib. N° 18256



Zona industriale Lotto 41 Via Montagna
72023 Mesagne (Br) – ITALY –
Tel: +39-0831777840 Fax +390831-730739
Sito web: www.promedicare.eu - e-mail: info@promedicare.it

Annex to the Declaration of
Conformity

All.Dic.Con.Sis.Sos.Con.Cap. EN
Rev.0 09/05/2024

Range Code - Description of the Device

SOLLIEVO	D00-010-X - Corona Model (A variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (21x9); 2: (28x13); 3: (40x18)
SOLLIEVO	D00-011-X - Corona Model with grippins system (B variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 0: (17x6); 1: (21x9); 2: (28x13); 3: (40x18)
SOLLIEVO	D00-012-X - Angelus Model (A variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (22x11); 2: (29x13); 3: (42x22)
SOLLIEVO	D00-013-X - Angelus Model with grippins system (B variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 0: (18x9); 1: (22x11); 2: (29x13); 3: (42x22)
SOLLIEVO	D00-014-X - Stilla A Model (A variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (15x9); 2: (20x12); 3: (29x17)
SOLLIEVO	D00-015-X - Stilla A Model with grippins system (B variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (15x9); 2: (20x12); 3: (29x17)
SOLLIEVO	D00-016-X - Stilla B Model (A variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (15x9); 2: (20x12); 3: (29x17)
SOLLIEVO	D00-017-X - Stilla B Model with grippins system (B variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (15x9); 2: (20x12); 3: (29x17)
SOLLIEVO	D00-018-X - Nubes A Model (A variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (11,5x15,5); 2: (15x18,5); 3: (21x28)
SOLLIEVO	D00-019-X - Nubes A Model with grippins system (B variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (11,5x15,5); 2: (15x18,5); 3: (21x28)
SOLLIEVO	D00-020-X - Nubes B Model (A variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (11,5x15,5); 2: (15x18,5); 3: (21x28)
SOLLIEVO	D00-021-X - Nubes B Model with grippins system (B variant) <u>TECHNICAL FEATURES:</u> D00: Sollievo Range X: size SIZE 1: (11,5x15,5); 2: (15x18,5); 3: (21x28)