

EU DECLARATION OF CONFORMITY

MANUFACTURER :

Corporate Name : NAUSICAA MEDICAL

Single registration number (SRN) : FR-MF-000000955

Head Office adress : ZA Pôle Actif-30660 GALLARGUES LE MONTUEUX

NAUSICAA MEDICAL :

- Certify that the UE declaration of conformity is issued under the sole of our responsibility as manufacturer
- Certifies that the devices mentioned below comply with Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017, on medical devices.

DEVICE :

Basic UDI-DI : 37014294PROBML

Product and trade name : BELT FOR BED SUPPORT

Model : PROBAR, PROBAR2

Product reference : PROBAR-M/L-PF, PROBAR2-M/L-PF

Intended purpose : medical devices for home care and daily living assistance for patients and people with disabilities (supporting and positioning patients in bed)

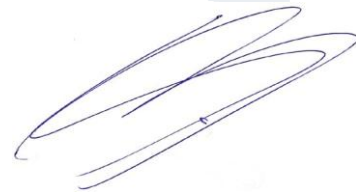
Risk class of the device (Annexe VIII) : Class I

Harmonised standards used and in relation to which conformity is declared :

- EN ISO 14971 : 2019 Medical devices - Application of risk management to medical devices
- EN ISO 15223-1 : 2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1 : General requirements

Place and date of the declaration :
Gallargues le Montueux, 18 August 2025

Name and position of signatory :
Bruce ANDURAND, Président



NAUSICAA MEDICAL

ZA Pôle Actif - 12 Allée du Piot - 30660 GALLARGUES-LE-MONTUEUX – France
Web : www.nausicaa-medical.com – Mail : contact@nausicaa-medical.com N°
Téléphone : 04 66 51 50 80 - Fax : 04 66 51 50 47
TVA : FR 954 208 72 293