

NAUSICAA

MEDICAL

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-FRANCE

NAUSICAA MEDICAL:

- certify that the UE declaration of conformity is issued under the sole of our responsibility as manufacturer

- confirms that the following devices are in conformity with the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices

DEVICE:

Basic UDI-DI : 37014294PB7S

Product and trade name : SIMPLE BIRDY BELT ; PELVIC COMFORT BELT ; MINI-PELVIC BELT ; PELVIC SLIM BELT

Model : CBR2HP ; CPCF3HP ; CPE2 ; CSP2HP

Products codes : CBR2HP-PF-S/M/L/XL ; CPCF3HP-PF-S/M/L ; CPE2-PF-S/M/L ; CSP2HPPF-80/95/110/130

Intended purpose : medical devices for home care and living aids for disabled patients (patient positioning)

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

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

EN ISO 14971 : 2012 Medical devices - Application of risk management to medical devices

EN ISO 15223-1 : 2016 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, 7th June 2022

Bruce ANDURAND
President

