

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 : 37014294BB6G

Product and trade name : Y SLIM BELT ; BUST SUPPORT BELT ; INTEGRAL JACKET ; YZA JACKET

Model : CSY2HP ; CMB2HP ; CGI3 ; YZA2GBHP ; YZA2

Products codes : CSY2HP-PF-80/95/110/130 ; CMB2HP-PF-S/M/L ; CGI3-PF-S/M/L ; YZA2GBHP-PF ; YZA2GBHP-PF + YZA2-MP-PF

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 : 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, 7th June 2022

Bruce ANDURAND
President

