

# 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

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**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

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**DEVICE:**

**Basic UDI-DI** : 37014294IB75

**Product and trade name** : INTEGRAL BIRDY BELT ; Y & PELVIC SLIM BELT ; INTEGRAL BODY HOLDER ; YZA BELT

**Model** : CBRIN2HP ; CSY2HP ; CBIM2HP ; YZA2CAHP ; YZA2

**Products codes** : CBRIN2HP-PF-S/M/L/XL ; CSY2HP-PF-80/95/110/130 ; CBIM2HP-PF-S/M/L/XL ; YZA2CAHP-PF ; YZA2-MP-PF ; YZA2-MB-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

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Place and date of the declaration

Gallargues le Montueux, 7<sup>th</sup> June 2022

Bruce ANDURAND  
President

