

DECLARATION DE CONFORMITE UE

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
- 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: 37014294CRELJF
Product and trade name : LIFTING BELT ; WALKING AID BELT, RAISING BELT
Model : CREL ; CADM2 ; SRL
Product code : CREL-PF-M/L ; CADM2-PF-S/M/L/XL ; SRL-PF

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

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, 26 August 2024

Bruce ANDURAND Président

