

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 : 37014294PLSLGUL2

Product and trade name : UNIVERSAL ECO SLING ; FAST ADJUSTABLE ECO SLING ; U-SHAPED SLING (COMFORT, BATH) ; FAST ADJUSTABLE SLING (COMFORT, BATH, WITH OR WITHOUT HEADREST) ; ENVELOPING SLING ; ERGONOMIC SLING ; XXL SLINGS

Model : SURPC ; SURP ; SUCBAS ; SUCBAI ; SML ; SMLBA ; SST ; SSTBA ; SLK ; SMB

Products codes : SURPC-PF-TU ; SURP-PF-TU ; SSTRP-PF-TU ; SUCBAS-PF-S/M/L/XL/2XL/3XL/4XL ; SUCBAI-PF-S/M/L/XL/2XL/3XL/4XL ; SML-PF-S/M/L/XL ; SMLBA-PF-S/M/L/XL/2XL/3XL/4XL ; SST-PF-S/M/L/XL ; SSTBA-PF-S/M/L/XL ; SLK-PF-S/M/L/XL ; SMB-PF-S/M/L/XL ; SUCBAIT-PF-2XL/3XL/4XL

Intended purpose : medical devices for home care and living aids for disabled patients (transfer of persons)

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

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

EN ISO 10535 : 2021 Hoists for the transfer of disabled persons - Requirements and test methods

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

