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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 responsability 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: 37014294SLSLGM8

Product and trade name : ECO SLING ; SPECIFIC SLING ; STANDARD SLING

Model: SXPECO; SWYP3; SAPVR

Products codes : SXPECO-PF-TU ; SWYP3-PF-S/M/L/XL/2XL/3XL/4XL ; SAPVR-PF-S/M/L/XL 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: 2006 Hoists for the transfer of disabled persons - Requirements and test methods 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, 30th March 2021

Clément CHAUZAT

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