

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

NAUSICAA MEDICAL :

- Certify that the UE declaration of conformity is issued under the sole of our responsibility as manufacturer
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DEVICE :

Basic UDI-DI : 37014294SANGLESECOXZ

Product and trade name : ECO SLING U SHAPE JERSEY COMFORT ONE SIZE FITS ; ECO SLING JERSEY MODEL ONE SIZE FITS ; ECO SLING BATH MODEL ONE SIZE FITS ; ECO JERSEY COMFORT TOILET SLING ONE SIZE FITS ; ECO HAMMOCK SLING JERSEY MODEL ONE SIZE FITS ; ECO HAMMOCK SLING BATH MODEL ONE SIZE FITS

Model : SURPC3 ; SUP3 ; SUP3P ; SURP3 ; STO ; HA ; HA3-RBA ; HAP

Product reference : SURPC3-PF-TU ; SUP3-PF-TU ; SUP3P-PF-TU ; SURP3-PF-TU ; STO-RP3-TU ; HA-PF-TU ; HA3-RBA-PF-TU ; HAP-PF-TU

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

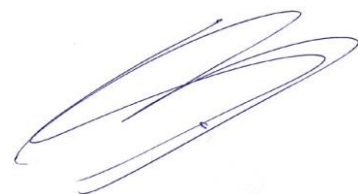
Risk class of the device (Annexe VIII) : Class I

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, 03 December 2024

Name and position of signatory :
Bruce ANDURAND, Président



NAUSICAA MEDICAL

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