

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 : 337014294PLSLGSPSX

Product and trade name : BACKREST TOILET SLING ; QUICK TOILET SLING ; BACKREST SLING ; ERGONOMIC SLING WITH HEADREST

Model : SATL ; STO ; STC ; SGLDOS ; SMB

Product reference : SATL-PF-S/M/L/XL ; STO-PF-S/M/L/XL ; STC-PF-S/M/L/XL ; SGLDOS-PF-S/M/L/XL ; SMB-PF-S/M/L/XL

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

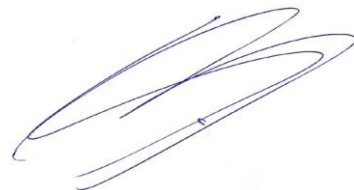
Risk class of the device (Annexe VIII) : Class I

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

- EN ISO 10535 : 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, 04 December 2024

Name and position of signatory :
Bruce ANDURAND, Président



NAUSICAA MEDICAL

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