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 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

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DEVICE:

Basic UDI-DI : 37014294ATTX

Product and trade name : FASTENERS

Model : LMATPO ; LMATPOS ; LMATCH

Products codes : LMATPO-PF ; LMATPOS-PF ; LMATCH-PF

Intended purpose : medical devices for home care and living aids for disabled patients (bed textile devices)

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

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Place and date of the declaration

Gallargues le Montueux, 7th June 2022

Bruce ANDURAND
President