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

NAUSICAA MEDICAL :

- Certify that the UE declaration of conformity is issued under the sole of our responsability as manufacturer
- Certifies that the devices mentioned below comply with Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017, on medical devices.

DEVICE :

Basic UDI-DI : 37014294NAUSIFLY4G8
Product and trade name : NAUSIFLY 4
Model : NAUSIFLY 4 with electrical opening legs
Product reference : NAFLY4+-CBLI

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
- EN 60601-1 :2006/A1 : 2013 Medical electrical equipment - Part 1 : General requirements for basic safety and essential performance
- EN 60601-1-2 : 2015 Medical electrical equipment - Part 1-2 : General requirements for basic safety and essential performance
- Collateral Standard: Electromagnetic disturbances - Require- ments and tests

Place and date of the declaration :
Gallargues le Montueux, 25 June 2025

Name and position of signatory :
Bruce ANDURAND, Président