

## EU DECLARATION OF CONFORMITY

### MANUFACTURER :

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Corporate Name : NAUSICAA MEDICAL

Single registration number (SRN) : FR-MF-000000955

Head Office adress : ZA Pôle Actif-30660 GALLARGUES LE MONTUEUX

### NAUSICAA MEDICAL :

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

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**Basic UDI-DI** : 37014294NAUSIFLY4G8

**Product and trade name** : NAUSIFLY 4

**Model** : NAUSIFLY 4 with mechanical 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

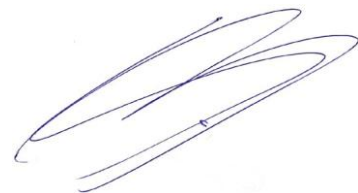
### Harmonised standards used and in relation to which conformity is declared :

- 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

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

Name and position of signatory :  
Bruce ANDURAND, Président



NAUSICAA MEDICAL

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