

# 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

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### NAUSICAA MEDICAL:

- certify that the UE declaration of conformity is issued under the sole of our responsibility 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** : 37014294FLYER300R8

**Product and trade name** : FLYER 300

**Model** : FLYER 300 with electrical opening legs

**Products codes** : FLYER300-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 - Requirements and tests

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Place and date of the declaration

Gallargues le Montueux, 7<sup>th</sup> June 2022

Bruce ANDURAND  
President

