

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 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 : 37014294NAUSIFLYZ7
Product and trade name : NAUSIFLY
Model : NAUSIFLY with mechanical opening legs
Products codes : NAFLY2-180-PF ; NAFLY2-180-LI-PF
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 : 2006 Hoists for the transfer of disabled persons - Requirements and test methods
EN ISO 14971 : 2012 Medical devices - Application of risk management to medical devices
EN ISO 15223-1 : 2016 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

Place and date of the declaration
Gallargues le Montueux, 29th March 2021

Clément CHAUZAT
President

