Phone: +33 (0) 466 717 184 Fax: +33 (0) 466 532 305

Email: export@nausicaa-medical.com

VAT N°: FR 954 208 72 293



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.

DEVICE:

Basic UDI-DI: 37014294WAYUP5MP Product and trade name: WAYUP 5

Model: WAYUP 5 with mechanical opening legs

Products codes: WAYUP5ECP-M-PF; WAYUP5ECP-M-LI-PF

Intended purpose: medical devices for home care and living aids for disabled patients (trans-

fer 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