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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: 37014294WAYUPXLXU Product and trade name: WAYUP XL

Model: WAYUP XL with electrical opening legs
Products codes: WAYUPXL-E-PF; WAYUPXL-E-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