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NAUSICAA MEDICAL

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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

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 : 37014294BLUEWAYUPECP323
Product and trade name : BLUE WAYUP 3 ECP ; BLUE WAYUP 3 ECP collapsible
Model : BLUE WAYUP 3 with electrical opening legs, BLUE WAYUP 3 with electrical opening legs collapsible
Product code : WAYBLUE+3-CBLI ; WAYBLUE+3S-CBLI ; BW3PLUS-CBLI

Accessories : WP PROTECTIVE COVER (HPD-WP) - ERGONOMIC SUB-ROTURAL SUPPORT (OPT-CTM-GO)

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

Place and date of the declaration
Gallargues le Montueux, 18th September 2024

Bruce ANDURAND President