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NAUSICAA Médical
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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-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 : 37014294NAUSIFLOWAUTOMGE
Product and trade name : NAUSIFLOW 100 MAXI SYSTEM
Model : NAUSIFLOW 100 MAXI (PUMP) ; NAUSIFLOW 100-834-120 (MATRESS)
Products codes : NA100MAXI-COMP-PM ; NA512-MAT85-PM ; NA834-MAT120-PM
Intended purpose : pressure ulcer prevention. Alleviation of an injury (pressure care systems)
Risk class of the device (Annexe VIII) : Class I
Harmonised standards used and in relation to which conformity is declared :
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
EN 60601-1-11 :2010 Medical electrical equipment - Part 1-11 : General requirements for basic safety and essential performance - Collateral standard : Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
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

Place and date of the declaration
Gallargues le Montueux, 30th March 2021

Clément CHAUZAT
President