

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 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

DEVICE :

Basic UDI-DI : 37014294TABALFS
Product and trade name : Removable, ribbed partial head support
Model : TABAL
Product code : TABAL-PF

Intended purpose : medical devices for homecare and assisted living for the sick and disabled. Medical devices and equipment for assisted living. Partial head support device

Risk class of the device (Annexe VIII) : Class I

Harmonised standards used and in relation to which conformity is declared :

- 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

Place and date of the declaration

Gallargues le Montueux, 16th February 2023

Bruce ANDURAND President

