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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: 37014294MF7R

Product and trade name: SECURITY MITTS; FOOT SUPPORT

Model: LMMFL; LMDP

Products codes: LMMFL-HP-PF; LMDP-HP-PF

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

positionning)

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

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

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