MediMattress Ltd
Haukilahdenkatu 4, Helsinki, Finland
T: +358 3 06404040
info@medimattress.fi
www.medimattress.fi

MediMattress Better Care
A DIRECT HEALTHCARE GROUP COMPANY

EU Declaration of Conformity

issued under the sole responsibility of MediMattress Ltd (Legal Manufacturer) confirms the requirements specified in the EU Medical Device Regulation 2017/745 (MDR) have been fulfilled for products listed in Appendix I of this document.

Legal Manufacturer Information	*MediMattress Ltd* *Haukilahdenkatu 4* *00550 Helsinki* *Finland* *Business ID: 1480110-8* *EUDAMED SRN: FI-MF-000009089*
Medical Device Registration Agency	*The Finnish Medicines Agency (Fimea)*
General Product Trade Name(s)	*See Appendix I*
Intended Use of Medical Device(s)	*Relaxing or calming down a restless or agitated patient for whom the healthcare professional has determined the need and assessed the medical device as appropriate for the patient and the treatment situation in question.*
EMDN Code	*Y1899*
Classification	*Class I (Rule 1 – Non-invasive devices)*
Assessment Route	*Annex II of the Medical Device Regulation (EU) 2017/745 (MDR)*
Applicable standards/ Common specifications	*See Appendix II*

Place and Date
Tampere, Finland - 8th of April 2022

Lauri Haavikko
PRRC
MediMattress Ltd

MediMattress Ltd
Haukilahdenkatu 4, Helsinki, Finland
T: +358 3 06404040
info@medimattress.fi
www.medimattress.fi

MediMattress Better Care
A DIRECT HEALTHCARE GROUP COMPANY

Appendix I – Product Listing

Products:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)
ProRelax	60PRE	642981059160PREWY

Appendix II – Applicable Standards

Following standards are used to fulfil the beforementioned requirements (MDR):

Standard/Document Name	Description
EN ISO 13485:2016	Medical devices — Quality management systems
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 10993-1:2018	Biological Evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 15223-1:2020	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 3758:2012	Textiles — Care labelling code using symbols

Revision log

Version	Date	Author	Amendment
1.0	25/05/2021	LH	First issue MDR compliance
1.1	06/07/2021	LH	Updated Basic UDI-DI to GMN-format, added EUDAMED SRN-info
1.2	08/04/2022	LH	Updated GMDN to EMDN, corrected typos