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)	*Supporting care as high-resilience furniture, bed accessories and mattresses for care environment in psychiatric healthcare and mental healthcare for the mentally handicapped, as well as in similar demanding healthcare and homecare environments.*
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 - 30th of December 2021

Lauri Haavikko
PRRC
MediMattress Ltd

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Appendix I – Product Listing

Products:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	EMDN Code
ProTyyny	60PTY	642981059160PTYYE	Y1899
ProLaitapehmuste	60PRD	642981059160PRDWW	Y1899
ProTäkki	60PTKI	642981059160PTKIZQ	Y1899
ProTuoli	60TUO	642981059160TUOYH	Y1899
ProKuutio	60KUU	642981059160KUUXG	Y1899
ProPatja	60PAT	642981059160PATWB	Y1899
ProSänky	60SAN	642981059160SANWE	Y1899

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	30/12/2021	LH	Separated from common document DOC-F-1.1.
1.1	08/04/2022	LH	Corrected typos