

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	<i>MediMattress Oy Haukilahdenkatu 4 00550 Helsinki Finland Business ID: 1480110-8 EUDAMED SRN: FI-MF-000009089</i>
Medical Device Registration Agency	<i>The Finnish Medicines Agency (Fimea)</i>
General Product Trade Name(s)	<i>See Appendix I</i>
Intended Use of Medical Device(s)	<i>Supporting care as temporal patient restrictors in psychiatric healthcare and mental healthcare for the mentally handicapped, as well as in similar demanding healthcare and homecare environments.</i>
Classification	<i>Class I (Rule 1 – Non-invasive devices)</i>
Assessment Route	<i>Annex II of the Medical Device Regulation (EU) 2017/745 (MDR)</i>
Applicable standards/ Common specifications	<i>See Appendix II</i>

Place and Date

Tampere, Finland - 8th of April 2022



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PRRC
MediMattress Ltd

Appendix I – Product Listing

Products:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	EMDN Code
ProLeposide	60PRB	642981059160PRBWS	Y1899
ProHaaravyö	60PRH	642981059160PRHX6	44851
ProTurva	60TUR	642981059160TURYP	10415

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. Changed GMDN codes to EMDN Code.
1.1	08/04/2022	LH	Corrected typos