

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	MediMattress Oy	
Information	Haukilahdenkatu 4	
	00550 Helsinki	
	Finland	
	Business ID: 1480110-8	
	EUDAMED SRN: FI-MF-000009089	
Medical Device	The Finnish Medicines Agency (Fimea)	
Registration Agency		
General Product Trade	See Appendix I	
Name(s)		
Intended Use of	Prevention of pressure ulcers or raising the sitting	
Medical Device(s)	position on level seat bases on low or low and	
	medium pressure ulcer risk category patients (not	
	incl. booster cushions), who has been assessed to	
	be in the defined pressure ulcer risk or is in other	
	need of care by an assessment by a healthcare,	
	preferably seating, professional.	
GMDN Code	V08030102	
Classification	Class I (Rule 1 – Non-invasive devices)	
Assessment Route	Annex II of the Medical Device Regulation (EU)	
	2017/745 (MDR)	
Applicable standards/	See Appendix II	
Common specifications		

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

n flan lake Lauri Haavikko

PRRC MediMattress Ltd



Appendix I – Product Listing

Products:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)
Exact5	30EXAK5	642981059130EXAK53H
Exact7	30EXAK7	642981059130EXAK73M
Exact2	30EX2	642981059130EX2TN
ExactL	30EXL	642981059130EXLV8
ExactXL	30EXX	642981059130EXXVY
ExactQ	30EXQ	642981059130EXQVJ
ExactHigh	30EXH	642981059130EXHUY
ExactHip	30EXP	642981059130EXPVG

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