MediMattress Ltd
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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)	*Prevention of pressure ulcers in the lying position on low or low and medium pressure ulcer risk category patients, who has been assessed to be in the defined pressure ulcer risk or is in other need of care by an assessment of a healthcare professional.*
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

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Appendix I – Product Listing

Parent products:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	EMDN Code
EkoAvec	10EKA	642981059110EKASM	V080702
EkoP	10EKP	642981059110EKPTK	V080702
EkoUltra/ Eko3	10EU/ 10EK3	642981059110EUXR/ 642981059110EK3RT	V080702
EkoUltraP	10EUP	642981059110EUPUH	V080702
EkoUltraXL	10UL4	642981059110UL4UG	V080702
EkoWave	10EWA	642981059110EWATR	V080702
EkoWaveP	10EWP	642981059110EWPUP	V080702
Eko2	10EK2	642981059110EK2RR	V080702
TergoSafe2	10TS2	642981059110TS2UU	V080702
TergoSafe3	10TS3	642981059110TS3UW	V080702
TergoSafe4	10TS4	642981059110TS4UY	V080702
TergoRTG	10RTG	642981059110RTGVV	V080702

With compatible accessories:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	EMDN Code
Matra	70MAT	642981059170MATW7	UO780
MediEva	70EVA	642981059170EVAVQ	V9099
ProEva	70PRE	642981059170PREXB	V9099

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

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Revision log

Version	Date	Author	Amendment
1.0	17/05/2021	LH	First issue MDR compliance
2.0	25/5/2021	LH	Template updated
2.1	06/07/2021	LH	Updated Basic UDI-DI to GMN-format, added EUDAMED SRN-info
2.2	08/04/2022	LH	Updated GMDN to EMDN, corrected typos