MediMattress Ltd
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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)	*Antideformation mattress system for prevention and therapy of pressure ulcers on high and very-high pressure ulcer risk category patients.*
Classification	*Class I (Rule 1 – Non-invasive devices, Rule 13 – All other active devices)*
Assessment Route	*Annex II of the Medical Device Regulation (EU) 2017/745*
Applicable standards/ Common specifications	*See Appendix II*

Place and Date
Tampere, Finland – 29th of May 2023

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
Optima7080	OP7	6429810591OP7D8	V080701
Optima8590	OP8	6429810591OP8DA	V080701
OptimaEZ	EZ1	6429810591EZ1C8	V080701
OptimaEZ420	EZ4	6429810591EZ4CE	V080701
OptimaAMP	OPA	6429810591OPADS	V080701
OptimaBario	OPB	6429810591OPBDU	V080701
OptimaHBO	OPH	6429810591OPHE8	V080701
NeoICU	NEI	6429810591NEID4	V080701
NeoIW	NEW	6429810591NEWDY	V080701
OptimaCot	OPC	6429810591OPCDW	V080701
OptimaJuve	OPJ	6429810591OPJEC	V080701
Opera I	OP1	6429810591OP1CU	V080701
Opera II	OP2	6429810591OP2CW	V080701

With compatible accessories:

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

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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
IEC 60601-1:2005 & IEC 60601-1:2005/AMD1:2012 excl. subclause 11.7	Medical electrical equipment – Part 1: General requirements for safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010 & IEC 60601-1-6:2010/AMD1:2013	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-11:2015	Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 62304:2006 & IEC 62304:2006/AMD1:2015	Medical Device — Software Life Cycle Processes
IEC 62366:2007 & IEC 62366:2007/AMD1:2014	Medical devices — Part 1: Application of usability engineering to medical devices
ISO 10993-1:2018	Biological Evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (Reference 9)
EN 12182:2012	Assistive products for persons with disability — General requirements and test methods
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
IEC 60601-2-52:2009 subclause 201.9.101	Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds (requirements concerning patient safety and mattress height)

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Revision log

Version	Date	Amendment
1.0	25/05/2021	First issue new template
1.1	01/07/2021	Manufacturer change, updated GTIN-13s, added missing classification rule 13, corrected typographical errors
1.2	06/07/2021	Updated Basic-UDI-DI to GMN-format, added EUDAMED SRN-info
1.3	08/04/2022	Changed GMDN codes to EMDN codes
1.4	29/05/2023	Corrected wrong manufacturer info in ingress section