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 Oy* *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 or raising the sitting 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/ Common specifications	*See Appendix II*

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

Lauri Haavikko
PRRC
MediMattress Ltd

MediMattress Ltd
Haukilahdenkatu 4, Helsinki, Finland
T: +358 3 06404040
info@medimattress.fi
www.medimattress.fi

MediMattress Better Care
A DIRECT HEALTHCARE GROUP COMPANY

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