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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)	*(TergoGlide) Repositioning, lateral transfer, gliding and/or lifting of patients lying down and whose moving capability is compromised. Incontinence protector pad.* *(Inko5) Incontinence protector pad.* *(TergoBelt) Accessory for TergoGlide. Supporting the operator in transfer situations.*
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
TergoGlide	50TEG	642981059150TEGW6	Z12011299

With compatible accessories (TergoGlide):

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	EMDN Code
TergoBelt	51TEB	642981059151TEBW3	Z12011299

Appendix II – Applicable Standards

Following standards are used to fulfil the beforementioned requirements (MDR):

Standard/Document Name	Description
(TergoGlide) EN ISO 10535:2006, 8.3	Hoists for the transfer of disabled persons — Requirements and test method
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	25/5/2021	LH	First issue MDR compliance
1.1	06/07/2021	LH	Updated Basic UDI-DI to GMN-format, added EUDAMED SRN-info, added TergoBelt Intended Use
1.2	08/04/2022	LH	Updated GMDN to EMDN, Inko5 removed, corrected typos