

## EU Declaration of Conformity

issued under the sole responsibility of MediMattress Oy (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.

<b>Legal Manufacturer Information</b>	<i>MediMattress Oy Haukilahdenkatu 4 00550 Helsinki Finland Business ID: 1480110-8 EUDAMED SRN: FI-MF-000009089</i>
<b>Medical Device Registration Agency</b>	<i>The Finnish Medicines Agency (Fimea)</i>
<b>General Product Trade Name(s)</b>	<i>See Appendix I</i>
<b>Intended Use of Medical Device(s)</b>	<i>(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.</i>
<b>Classification</b>	<i>Class I (Rule 1 – Non-invasive devices)</i>
<b>Assessment Route</b>	<i>Annex II of the Medical Device Regulation (EU) 2017/745</i>
<b>Applicable standards/ Common specifications</b>	<i>See Appendix II</i>

### Place and Date

Tampere, Finland - 6<sup>th</sup> of July 2021



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## Appendix I – Product Listing

### Parent products:

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	GMDN Code
TergoGlide	50TEG	642981059150TEGW6	37455
Inko5	80PI5	642981059180PI5VV	37165

### With compatible accessories (TergoGlide):

Trade Name	Manufacturer REF	Basic UDI-DI (GMN)	GMDN Code
TergoBelt	51TEB	642981059151TEBW3	37455

## 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