EU/UK/AU/CH Declaration of Conformity
DC0044 Rev. 03

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Manufacturer Information:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA SRN: US-MF-000012287
Person Responsible for Regulatory Compliance (PRRC):	Chris Rahn, Sr. Director RA/QA
European Union (EU) Authorized Representative Contact Information:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany Phone : (+49) 511 6262 8630 SRN: DE-AR-000005430
United Kingdom (UK) Responsible Person Contact Information:	Emergo Consulting (UK) Limited c/o Cr360 UL International Compass House, Vision Park Histon Cambridge CB24 9BZ, United Kingdom Phone: +44(0) 1223 772 671
Swiss (CH) Authorized Representative Contact Information:	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland CHRN: CHRN-AR-20001035.
Product identification:	Hipsters and Floor Cushions
Technical File No.:	TF-0028 Fall Management
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate
EU Legislation and Conformity Assessment Procedure:	Annex II & Annex III: Technical documentation including PMS of Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.
UK Legislation and Conformity Assessment Procedure:	NA - Not marketing in UK
Australia (AU) Legislation and Conformity Assessment Procedure:	Clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods Administration Medical Device Regulation 2002.
CH Legislation and Conformity Assessment Procedure:	Annex II & Annex III: Technical documentation including PMS of Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.
Intended purpose:	Hipsters® are intended to reduce the risk of patient hip fracture injury due to a fall. Floor Cushions are intended to reduce the risk of injury due to a

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	patient fall from the bed .	
EMDN Code:	V080601 – Electric Medical beds	
Basic UDI-DI:	Basic UDI-DI for Fall Management: Hipsters 0190676TF-0028-A4M Floor Cushions 0190676TF-0028-B4P	
Device Classification/ Rule in EU/CH:	Risk Class I	Rule 1
Device Classification/ Rule in UK:	NA - Not marketing in UK	
Device Classification/ Rule in Australia (AU):	Class I, Rule 2.1	
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	NA	
EC Certificate: *If self-declared add "N/A Self-Declared."*	Number: N/A Self-Declared	Issue Date: N/A Self-Declared
UKCA Certificate: *If self-declared add "N/A Self-Declared"*	Number: N/A Self-Declared	Issue Date: N/A Self-Declared
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 29 May 2023
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 29 May 2023
Notified Body for QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands NB No. 2797	
Notified Body for EU Conformity Assessment:	NA	
Approved Body for UK Conformity Assessment:	NA	

For European Union (Non-sterile products)

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC.
The undersigned hereby declares, on behalf of TIDI Products, LLC, that the medical devices referenced in this declaration comply with the European Medical Devices Regulation; MDR (EU) 2017/745. We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

For Australia (Non-sterile products):

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This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC. The undersigned hereby declares, on behalf of TIDI Products, LLC, that each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, and the classification rules before being supplied under clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods Administration Medical Device Regulation 2002.

For Switzerland:

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC. The undersigned hereby declares, on behalf of TIDI Products, LLC, that the medical devices referenced in this declaration comply with the applicable parts of the MedDO. These are class I medical devices that declare conformity to Regulation (EU) 2017/745 (MDR.) We explicitly designate MDSS CH GmbH to act as our sole Authorised Representative in Switzerland for the above indicated products.

Signed for on behalf of TIDI Products LLC, in Neenah, WI 54956		
Name of TIDI Representative: Brenda Ammonette	**Title, Function**	**Date**
Approval: *Brenda Ammonette*	**Approval:** Regulatory Compliance Manager	July 12,02023

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
6026	Beveled Floor Cushion	30035	00190676000425
6027	Beveled Floor Mat	30035	00190676000432
6016S	Hipsters, Std. Brief, Small	36312	00190676005871
6016L	Hipsters, Std. Brief, Large	36312	00190676005826
6016M	Hipsters, Std. Brief, Medium	36312	00190676005833
6016RS	Hipsters, Std. Brief, Removable Pads, S	36312	00190676005864
6016XL	Hipsters, Std. Brief, Xlarge	36312	00190676005888
6016XXL	Hipsters, Std. Brief, XXlarge	36312	00190676005895
6017L	Incont. Hipsters, Large	36312	00190676006137
6017M	Incont. Hipsters, Medium	36312	00190676006144

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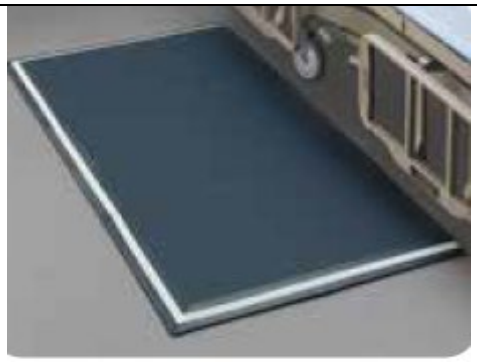
Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
6017S	Incont. Hipsters, Small	36312	00190676006151
6017XL	Incont. Hipsters, Extra Large	36312	00190676006168
6027R	Beveled Floor Mat W/Reflective Tape	30035	00190676000876

Product Name	Photo (if appropriate)
Hipsters	
Floor Cushions	

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
30035	Floor covering, non-conductive, special
36312	Hip protection trousers