



Declaration of Conformity DC0044 Rev. 1

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

Manufacturer Information Name, Address, SRN:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA	SRN: TBD				
Name of responsible person (PRRC) or designee:	Name: Steve Kahn	Title: VP of Quality and Regulatory				
Authorized Representative Contact Information:	Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover Germany	SRN: DE-AR-000005430				
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.					
Technical File No.:	TF-0028 Fall Management					
Product Identification:	Hipsters and Floor Cushions					
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate					
Basic UDI-DI/ Intended purpose:	<p>Hipsters® are intended to reduce the risk of patient hip fracture injury due to a fall.</p> <p>Floor Cushions are intended to reduce the risk of injury due to a patient fall from the bed</p> <p>Basic UDI-DI for Fall Management:</p> <table> <tr> <td>Hipsters</td> <td>0190676TF-0028-A4M</td> </tr> <tr> <td>Floor Cushions</td> <td>0190676TF-0028-B4P</td> </tr> </table>		Hipsters	0190676TF-0028-A4M	Floor Cushions	0190676TF-0028-B4P
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Floor Cushions	0190676TF-0028-B4P					
Device Classification/Rule:	Risk Class I	Rule 1				
Reference to Common Specifications:	N/A					
EC Certificate: <i>If self-declared add "N/A Self-Declared".</i>	Number: N/A Self-Declared	Issue Date: N/A Self-Declared				
Quality Management Certificate:	Number: FM 536366	Effective Date: 29 May 2020				
Notified Body Information for QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands					



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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 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.


Signed for on behalf of TIDI Products LLC, in Neenah, IL

Name of Authorized Person:	Title:	Date:
Approval:	Manager of Regulatory Compliance	23 June 2021

Model Number (REF)	Product Name	GMDN	UDI-DI
6026	Beveled Floor Cushion	30035	00190676000425
6027	Beveled Floor Mat	30035	00190676000432
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
6017S	Incont. Hipsters, Small	36312	00190676006151
6027R	Beveled Floor Mat W/Reflective Tape	30035	00190676000876

Product Name	Photo (if appropriate)
Hipsters	

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<p>Floor Cushions</p>	
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GMDN	Term
30035	Floor covering, non-conductive, special
36312	Hip protection trousers