EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

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, Senior Director Quality and Regulatory
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:	Restraints and Restraint Alternatives
Technical File No.:	TF-0026 Restraints and Restraint Alternatives
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photos, 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:	UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). Conformity to Part II of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002).
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.

EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

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:	The Restraints and Restraint Alternatives are non-sterile devices. Mitts are restraint alternatives worn on the hand and are designed to minimize the patient's ability to grasp objects external to the mitt. Limb Holders, Cuffs, and Connecting Straps are restraints used to limit limb movement and may be worn on the wrist or ankle for bed and/or stretcher use. Belts are restraints for chair, hospital bed, stretcher, wheelchair, or geri-chair use. Vests and Jackets are restraints and positioning devices that are used to assist in medical treatment and minimize risk that occurs from a fall.	
EMDN Code:	T030599 - Health Service Premises Protection Devices - Other	
Basic UDI-DI:	Basic UDI-DI for Restraint and Restraint Alternatives: Mitts 0190676TF-0026-A4B Limb holders 0190676TF-0026-C4F Belt 0190676TF-0026-D4H Jacket/Vest 0190676TF-0026-E4K	
Device Classification/ Rule in EU/CH:	Risk Class I	Rule 1
Device Classification/ Rule in UK:	Risk Class I	Rule 1
Device Classification/ Rule in Australia (AU):	Risk 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: NA Self-Declared	Issue Date: NA Self-Declared
UKCA Certificate: *If self-declared add "N/A Self-Declared"*	Number: NA Self-Declared	Issue Date: NA 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

EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

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 United Kingdom:

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 UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).). We explicitly designate Emergo Consulting (UK) Limited to act as our sole Responsible Person in the UK for the above indicated products.

For Australia (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 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 in Neenah, WI. 54956

Name of TIDI Representative: Brenda Ammonette	**Title, Function**	**Date**
Approval: *Brenda Ammonette*	**Approval:** Regulatory Compliance Manager	July 10, 2023

EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
1135	Posey Self Releasing Roll Belt	62482	00190676003365
1231	Posey Roll Belt	62482	00190676003808
1334	Posey Key Lock Belt	62482	00190676003792
1337	Swedish Belt, One Size Fits All	62482	00190676002788
2510	Posey Economy Soft Limb holders	62482	00190676005291
2530	Posey Foam Soft limb holders	62482	00190676002887
2531	Posey Quick Release soft limb holders	62482	00190676004942
2532	Posey Quick release soft limb holders	62482	00190676004782
2533	Posey Quick release soft limb holders	62482	00190676005307
2534	Posey Quick release soft limb holders	62482	00190676005314
2550	Posey Quick release quilted soft limb holders	62482	00190676004935
2551	Posey Quick Release Quilted Limb Holder	62482	00190676004959
2552	Posey Quick release quilted soft limb holders	62482	00190676005345
2631	Posey deluxe soft limb holders	62482	00190676005369
2750	Twice as Tough Cuff for Gurney, Wrist	62482	00190676002818
2755	Twice as Tough Cuff for Gurney, Ankle	62482	00190676002825
2790	Twice as Tough Cuff, Wrist no Lock	62482	00190676002511
2791	Twice as Tough Cuff, Ankle no Lock	62482	00190676002832
2792	Twice as Tough Cuff, Wrist	62482	00190676002719
2793	Twice as Tough Cuff, Ankle	62482	00190676002726
2794	Twice as Tough Cuff, Connected Wrist	62482	00190676002733

EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
2795	Twice as Tough Cuff, Connected Ankle	62482	00190676002740
2798	Twice as Tough Cuff Wrist, Double Lock	62482	00190676002702
2799	Twice as Tough Cuff Ankle, Double Lock	62482	00190676002696
2809	Posey Mitts	62482	00190676005376
2810	Posey soft hand Mitts	62482	00190676005383
2811	Posey Peek-A-Boo Mitts	62482	00190676004799
2814	Posey Double security Mitts	62482	00190676004812
2816	Posey finger control Mitts	62482	00190676004836
2819	Posey Double security Mitts	62482	00190676004867
4125	Posey Soft Belt, Standard	62482	00190676003440
4733	Posey pediatric soft limb holders	62482	00190676003358
4734	Posey pediatric soft limb holders	62482	00190676003341
4749	Posey Circumstraint board straps	62482	00190676003235
5550	Posey General purpose belt, gurney	62482	00190676001088
5551	Posey Disposable Operating Room Body/Knee Strap	62482	00190676001125
1135QR	Posey Self releasing roll Belt	62482	00190676002757
1135QXL	Posey Self releasing roll Belt	62482	00190676005475
1231Q	Posey roll Belt	62482	00190676002764
1231QXL	Posey roll Belt	62482	00190676002771
2790Q	Quick Release TAT	62482	00190676003372
2791Q	Quick Release TAT	62482	00190676003204
2792Q	Locking TAT	62482	00190676003617

EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

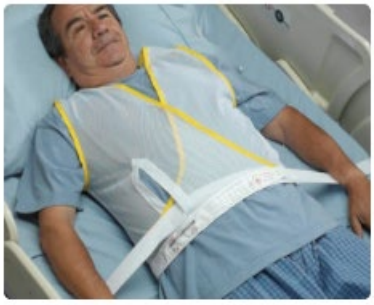
Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
2795L	TAT Cuff, Ankle, Long	62482	00190676005086
3050L	New Vest, Poly/Cotton Plaid	62482	00190676002542
3050M	New Vest, Poly/Cotton Plaid	62482	00190676002535
3050S	New Vest, Poly/Cotton Plaid	62482	00190676002528
3050XL	New Vest, Poly/Cotton Plaid	62482	00190676002559
3050XXL	Posey Safety Vest	62482	00190676002566
3060L	New Vest w/Quick Release Buckle	62482	00190676002610
3060M	New Vest w/Quick Release Buckle	62482	00190676002603
3060S	New Vest w/Quick Release Buckle	62482	00190676002597
3060XL	New Vest w/Quick Release Buckle	62482	00190676002627
3060XXL	New Vest w/Quick Release Buckle	62482	00190676002634
3063L	Safety Vest, Breezeline Mesh with QR Straps	62482	00190676003402
3063M	Safety Vest, Breezeline Mesh with QR Straps	62482	00190676003396
3063S	Safety Vest, Breezeline Mesh with QR Straps	62482	00190676003389
3063XL	Safety Vest, Breezeline Mesh with QR Straps	62482	00190676003419
2792Q	Locking TAT	62482	00190676003617
2795L	TAT Cuff, Ankle, Long	62482	00190676005086
3050L	New Vest, Poly/Cotton Plaid	62482	00190676002542
3050M	New Vest, Poly/Cotton Plaid	62482	00190676002535
3050S	New Vest, Poly/Cotton Plaid	62482	00190676002528
3050XL	New Vest, Poly/Cotton Plaid	62482	00190676002559

EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
3050XXL	Posey Safety Vest	62482	00190676002566
3060L	New Vest w/Quick Release Buckle	62482	00190676002610
3656XXL	Posey Torso Support, XXLarge	62482	00190676003600
3658M-L	Posey Wrap Around Medium-Large	62482	00190676001002
3658S-M	Posey Wrap Around Small-Medium	62482	00190676003570
3658XL	Posey Wrap Around X-Large	62482	00190676001026
3658XXL	Posey Wrap Around XX-Large	62482	00190676001033
4116PQ	Posey Self Releasing Omni Belt	62482	00190676003556
4125C	Posey Pelvic Soft Belt	62482	00190676003457
4125L	Posey soft belt, extra long	62482	00190676003464
4125Q	Posey soft belt, standard	62482	00190676003471
4126Q	Posey soft releasing padded belt	62482	00190676003488
4126V	Posey soft releasing padded belt	62482	00190676003495
5550B	Posey General purpose belt, bed	62482	00190676001101

Product Name	Photo (if appropriate)
Mitts	

EU/UK/AU/CH Declaration of Conformity
DC0042 Rev. 04

Limb Holders	
Belt	
Jacket/Vest	

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
62482	Limb/Torso/Head Restraint, reusable