EU/UK/AU/CH Declaration of Conformity

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, Vice President 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.
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.

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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.	
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 Posey Movable ID Bracelet (Newborn) 00190676002269	
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
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	

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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	June 12, 2025

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies

Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
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

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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**
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
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

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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**
2819	Posey Double security Mitts	62482	00190676004867
4648	Posey Movable ID Bracelet (Newborn)	32048	00190676002269
4733	Posey pediatric soft limb holders	62482	00190676003358
4734	Posey pediatric soft limb holders	62482	00190676003341
4749	Posey Circumstraint board straps	62482	00190676003235
2790Q	Quick Release TAT	62482	00190676003372
2791Q	Quick Release TAT	62482	00190676003204
2792Q	Locking TAT	62482	00190676003617
2795L	TAT Cuff, Ankle, Long	62482	00190676005086

Product Name	Photo (if appropriate)
Mitts	
Limb Holders	

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Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
62482	Limb/Torso/Head Restraint, reusable
32048	Patient Identification Band