



Declaration of Conformity DC0021 Rev. 02

Manufacturer and Contact:	TIDI Products LLC 570 Enterprise Drive Neenah, WI 54956 USA	Management Representative: Brenda Ammonette Regulatory Compliance Manager
Authorized Representative:	MDSS GmbH Schiffgraben 41 30175 Hannover, Germany	Telephone: 49 511 6262 8630
Conformity Assessment Procedure:	Annex VII of MDD 93/42/EEC Council Directive as amended by directive 2007/47/EC	
Technical File No.:	TF-0026 Restraints and Restraint Alternatives	
Product Scope:	Restraints and Restraint Alternatives	
Model Numbers:	See following page(s) for model numbers, GMDNs, and descriptions.	
Device Classification:	Class 1	Rule 1
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 for Quality Management Certificate:	BSI Group The Netherlands B.V.	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Telephone: +31 20 346 0780 Notified Body Number: 2797

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 Directive 93/42/EEC as amended by directive 2007/47/EC, and its relevant transposition into national laws of the member states into which the devices are placed. 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, by the Manager of Regulatory Compliance, Brenda Ammonette, in Lake Forest, Illinois.

Name of Authorized Person	Title	Date
Approval: <i>Brenda Ammonette</i>	Regulatory Compliance Manager	01 Dec 2020



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Product Model Numbers, GMDN, and Description to which this declaration applies

Model Numbers	GMDN	Description
1035	62482	Posey Quick Release buckles
1040	62482	Posey Quick Release buckles
2510	44851	Posey Economy Soft Limb holders
2520	44851	Posey Double Strap Foam Soft Limb holders
2526	44851	Soft felt soft limb holders
2528	44851	Posey Double Strap Foam Soft Limb Holders
2530	44851	Posey Foam Soft limb holders
2531	44851	Posey Quick Release soft limb holders
2532	44851	Posey Quick release soft limb holders
2532/A	44851	Posey Quick release soft limb holders
2533	44851	Posey Quick release soft limb holders
2534	44851	Posey Quick release soft limb holders
2540	44851	Posey Deluxe Quilted Soft Limb Holders
2541	44851	Posey Deluxe Quilted Soft Limb Holders
2550	44851	Posey Quick release quilted soft limb holders
2551/A	44851	Posey Quick release quilted soft limb holders
2552	44851	Posey Quick release quilted soft limb holders
2554	44851	Posey Quick release quilted soft limb holders
2625	44851	Posey deluxe soft limb holders
2631	44851	Posey deluxe soft limb holders
4642	32858	Posey Elbow splint (Infant)
4643	32858	Posey Elbow splint (Pediatric)
4660	44851	Posey Chin strap
4733	44851	Posey pediatric soft limb holders
4734	44851	Posey pediatric soft limb holders
4749	62482	Posey Circumstraint board straps
6550	57982	Posey Incontinence sheath holder
6554	44851	Posey Soft Limb Restraints and Holders
6554/P	44851	Posey Pulse Oximeter probe wraps
8141	44851	Posey IV Shield
8142	58919	Posey Drainage bag strap
8143	57982	Posey Catheter tube holder strap
8161	62482	Posey Attachment clip for posey secure sleeve
8162	62482	Posey X-ray translucent clip for secure sleeve
8166	37047	Posey IV arm boards (Infant)
8167	37047	Posey IV arm boards (Pediatric)
8168	63273	Posey secure sleeve
8169	63273	Posey leg secure sleeve
8170	63273	Posey Pediatric soft splint
8196	35815	Posey Secure Ties
8197	35815	Posey Foam Trach Ties
25251	44851	Posey Padded Soft Limb holders
25281	44851	Posey Padded Soft Limb holders
1135	62482	Posey Self releasing roll Belt
1135QR	62482	Posey Self releasing roll Belt



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Model Numbers	GMDN	Description
1135QXL	62482	Posey Self releasing roll Belt
1201	62482	Posey roll Belt
1231	62482	Posey roll Belt
1231Q	62482	Posey roll Belt
1231QXL	62482	Posey roll Belt
1332	62482	Posey Slider Belt
1334	62482	Posey Key Lock Belt
1337	62482	Posey Swedish Belt
1731S	62482	Posey Body Holder, Small
1731M	62482	Posey Body Holder, Medium
1731L	62482	Posey Body Holder, Large
1731XL	62482	Posey Body Holder, X-Large
3658	62482	Posey Belts and Holders
3656	62482	Posey Belts and Holders
3658S-M	62482	Posey SR Wrap Around Small-Medium
3658M-L	62482	Posey SR Wrap Around Medium-Large
3658XL	62482	Posey SR Wrap Around X-Large
3658XXL	62482	Posey SR Wrap Around XX-Large
3659L	62482	Posey Self Releasing Wrap around, Large
3659XXL	62482	Posey Self Releasing Wrap around, XX-Large
4116PQ	62482	Posey Self Releasing Omni Belt
4125	62482	Posey Soft Belt, Standard
4125C	62482	Posey Pelvic Soft Belt
4125L	62482	Posey soft belt, extra long
4125Q	62482	Posey soft belt, standard
4126Q	62482	Posey soft releasing padded belt
4126V	62482	Posey soft releasing padded belt
4127	62482	Posey padded belt, with airline buckle
4130	62482	Posey lap belt with slide buckle
4135	62482	Posey padded belt, with slide buckle
4183	62482	Posey airline buckle belts
4183L	62482	Posey airline buckle belts
4184	62482	Posey hook and loop belts
4220	62482	Posey airline buckle belt
4222	62482	Posey airline buckle belt
4228	62482	Posey hook and loop belt
4228L	62482	Posey hook and loop belt, large
4229	62482	Posey airline buckle belt
4411S	62482	Posey Breezeline pelvic holder, small
4411M	62482	Posey Breezeline pelvic holder, medium
4411L	62482	Posey Breezeline pelvic holder, large



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Model Numbers	GMDN	Description
4427S	62482	Posey Breezeline pelvic holder, small
4427M	62482	Posey Breezeline pelvic holder, medium
4427L	62482	Posey Breezeline pelvic holder, large
4430S	62482	Posey foam pelvic holder, small
4430M	62482	Posey foam pelvic holder, medium
4430L	62482	Posey foam pelvic holder, large
4648	32048	Movable I.D. Bracelets (New Born)
4649	32048	Movable I.D. Bracelets (Preemie)
5145	62482	Posey airline buckle belts
5150	62482	Posey quick release belt
5550	62482	Posey General purpose belt, gurney
5550B	62482	Posey General purpose belt, bed
5551	44851	Posey Disposable Operating Room Body/Knee Strap
52105PQ	62482	Posey Quick Release Belt, one-piece loop
52106PQ	62482	Posey Quick Release Belt, one-piece loop
2809	62482	Posey Mitts
2810	62482	Posey soft hand Mitts
2811	62482	Posey Peek-A-Boo Mitts
2813	62482	Posey Secure Mitts
2814	62482	Posey Double security Mitts
2815	62482	Posey finger control Mitts
2816	62482	Posey finger control Mitts
2817	62482	Posey EZ-On Mitts
2819	62482	Posey Double security Mitts
2820	62482	Posey Rigid hand control Mitts
2826	62482	Posey economy Mitts
2911	62482	Posey Mitts

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	Term
44851	Limb/Torso/Head Restraint, single use
62482	Limb/Torso/Head Restraint, reusable
32858	Elbow Protector
58919	Wearable urine collection bag, closed-ended
57982	Urinary catheter holder
63273	First aid limb splint, mouldable reusable
37047	Arm procedure positioner, reusable
35815	Endotracheal tube holder
32048	Patient Identification Band



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The products to which this declaration relates are developed and manufactured in conformity with the following standard(s).

Safety Standard	Title
ISO 13485	Quality Management System