



EU/UK/AU/CH Declaration of Conformity

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

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| 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 (SI 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: | <p>The Restraints and Restraint Alternatives are non-sterile devices.</p> <p>Mitts are restraint alternatives worn on the hand and are designed to minimize the patient's ability to grasp objects external to the mitt.</p> <p>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.</p> <p>Belts are restraints for chair, hospital bed, stretcher, wheelchair, or geri-chair use.</p> <p>Vests and Jackets are restraints and positioning devices that are used to assist in medical treatment and minimize risk that occurs from a fall.</p> | | | | | | | | | |
| EMDN Code: | T030599 - Health Service Premises Protection Devices - Other | | | | | | | | | |
| Basic UDI-DI: | <p>Basic UDI-DI for Restraint and Restraint Alternatives:</p> <table> <tr> <td>Mitts</td> <td>0190676TF-0026-A4B</td> </tr> <tr> <td>Limb holders</td> <td>0190676TF-0026-C4F</td> </tr> <tr> <td>Belt</td> <td>0190676TF-0026-D4H</td> </tr> <tr> <td>Jacket/Vest</td> <td>0190676TF-0026-E4K</td> </tr> </table> | | Mitts | 0190676TF-0026-A4B | Limb holders | 0190676TF-0026-C4F | Belt | 0190676TF-0026-D4H | Jacket/Vest | 0190676TF-0026-E4K |
| 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: <i>If self-declared add "N/A Self-Declared".</i> | Number: NA Self-Declared | Issue Date: NA Self-Declared | | | | | | | | |
| UKCA Certificate: <i>If self-declared add "N/A Self-Declared".</i> | 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: | <p>BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands NB No. 2797</p> | | | | | | | | | |



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| Notified Body for EU Conformity Assessment: | NA | |
| Approved Body for UK Conformity Assessment: | NA | |
| For European Union (Non-sterile products) | | |
| <p>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.</p> | | |
| For United Kingdom: | | |
| <p>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.</p> | | |
| For Australia (Non-sterile products): | | |
| <p>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.</p> | | |
| For Switzerland: | | |
| <p>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 Authorized Representative in Switzerland for the above indicated products.</p> | | |
| Signed for on behalf of TIDI Products LLC, in in Neenah, WI. 54956 | | |
| Name of TIDI Representative: Brenda Ammonette | Title, Function | Date |
| Approval: <i>Brenda Ammonette</i> | Approval: Regulatory Compliance Manager | November 18, 2024 |

| 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 |



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|--|---|-------|----------------|
| Model Number (REF) | Product Name | GMDN | UDI-DI |
| 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 |
| 2795 | Twice as Tough Cuff, Connected Ankle | 62482 | 00190676002740 |
| 2798 | Twice as Tough Cuff Wrist, Double Lock | 62482 | 00190676002702 |



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|--|---|-------|----------------|
| Model Number (REF) | Product Name | GMDN | UDI-DI |
| 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 |
| 2795L | TAT Cuff, Ankle, Long | 62482 | 00190676005086 |
| 3050L | New Vest, Poly/Cotton Plaid | 62482 | 00190676002542 |






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|--|---|-------|----------------|
| Model Number (REF) | Product Name | GMDN | UDI-DI |
| 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 |
| 3656XXL | Posey Torso Support, XXL Large | 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 |

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|--|----------------------------------|-------|----------------|
| Model Number (REF) | Product Name | GMDN | UDI-DI |
| 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 |  |
| Limb Holders |  |
| Belt |  |

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| | |
|--------------------|---|
| <p>Jacket/Vest</p> |  |
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| Glossary of Global Medical Device Nomenclature (GMDN) Terms | |
|---|-------------------------------------|
| GMDN | Term |
| 62482 | Limb/Torso/Head Restraint, reusable |