TACMED SOLUTIONS™, LLC

# DECLARATION OF CONFORMITY

**Manufacturer:** **TacMed Solutions™, LLC**
**1250 Harris Bridge Road, Anderson, SC 29621, USA**

**Product:** **Litters**
**Trademark(s):**

- **RESCUE TASK FORCE LITTER (RTFL)**
- **FOXTROT® LITTER (F-LITC)**
- **FOXTROT® DA (F-LITC-DA)**
- **PHANTOM® LITTER (PHL-K)**
- **PHANTOM® LITTER REFILL (PHL)**
- **TACMED™ POLELESS LITTER (POLIT)**
- **ULTRALIGHT POLELESS LITTER (ULPOLIT)**
  **(see following page for details and UDI)**

**Classification: Class 1 Non-Sterile – According to Annex VIII**

*Hereby we declare that the above-mentioned product meets the provision of the stated EU Medical Device Regulation 2017/745 and Harmonized Standards. All supporting documents are retained under the premises of the manufacturer and the authorized representative(s).*

**Harmonized Standard(s) and Documents Referenced:**

| | |
|---|---|
| EU MDR 2017/745 | European Medical Device Regulation 2017/745 |
| ISO 13485:2016 & EN ISO 13485:2016 | Medical Devices – Quality Management Systems – Requirements for regulatory purposes |
| FDA GMP - 21 CFR Part 820 | Quality System Regulation QSR Requirements for Medical Device Manufacturers. |
| EN 1041:2008 + Amd A1:2013 | Information supplied by the manufacturer with medical devices |
| EN 15223:2021 | Medical Devices – Symbols to be used with medical device labels, labelling, and information to be supplied. |
| EN ISO 14971:2019 | Medical devices. Application of risk management to medical devices |

**EU Authorized Representative:**

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**Technical File Number TF006**

Alan Hester, Chief of Staff - TacMed Solutions™, LLC
Approval Date: 25 MAR 2024

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| SKU | UDI / GTIN | Product Description |
|---|---|---|
| PHL-K, ACU | 00818630010487 | PHANTOM LITTER, COMPLETE KIT - ACU |
| PHL-K, BK | 00818630010494 | PHANTOM LITTER, COMPLETE KIT - BLACK |
| PHL-K, MC | 00818630010500 | PHANTOM LITTER, COMPLETE KIT - MULTI CAM |
| PHL-K, TAN | 00818630010517 | PHANTOM LITTER, COMPLETE KIT - TAN |
| F-LITC-A | 00818630010524 | FOXTROT LITTER & CARRIER (ACU) |
| F-LITC-B | 00818630010531 | FOXTROT LITTER & CARRIER (BLACK) |
| F-LITC-R | 00818630010548 | FOXTROT LITTER & CARRIER (RESCUE) |
| F-LITC-T | 00818630010555 | FOXTROT LITTER & CARRIER (TAN) |
| F-LITC-DA-A | 00818630010562 | FOXTROT LITTER AND CARRIER- DA (ACU) |
| F-LITC-DA-B | 00818630010579 | FOXTROT LITTER AND CARRIER- DA (BLACK) |
| F-LITC-DA-T | 00818630010586 | FOXTROT LITTER AND CARRIER- DA (TAN) |
| PHL | 00818630010593 | PHANTOM LITTER REFILL |
| POLIT | 00818630010609 | TAC MED POLELESS LITTER |
| PHL-K, G | 00818630012672 | PHANTOM LITTER, COMPLETE KIT - Green |
| RTFL | 00818630013693 | Rescue Task Force Litter |
| F-LITC-DA-RO | 00818630014027 | FOXTROT LITTER AND CARRIER- DA (RESCUE ORANGE) |
| RTFLC-T | 00818630014164 | Rescue Task Force Litter with Tan Carrier |
| RTFLC-B | 00818630014171 | Rescue Task Force Litter with Black Carrier |
| ULPOLIT | 00818630014195 | ULTRA LIGHT POLELESS LITTER - BLACK |
| F-LITC-RO | 00818630014508 | FOXTROT LITTER & CARRIER (RESCUE ORANGE) |
| F-LITC-RED | 00818630014515 | FOXTROT LITTER & CARRIER (RED) |
| F-LITC-DA-RED | 00818630014522 | FOXTROT LITTER AND CARRIER- DA (RED) |
| F-LITC-DA-OD | 00818630014539 | FOXTROT LITTER AND CARRIER- DA (OD GREEN) |
| F-LIT | 00818630014546 | FOXTROT LITTER NO CARRIER |
| F-LIT-DA | 00818630014553 | FOXTROT DA LITTER- LITTER ONLY |
| F-LIT-DA-TRN | 00818630014560 | FOXTROT LITTER DA TRAINER |
| F-LIT-TRN | 00818630014577 | FOXTROT LITTER TRAINER |
| F-LITC-OD | 00818630014584 | FOXTROT LITTER & CARRIER (OD GREEN) |
| RTFL | 00818630014607 | Rescue Task Force Litter (No Carrier) |
| RTFLC-B | 00818630014614 | Rescue Task Force Litter with Black Carrier |
| RTFLC-T | 00818630014621 | Rescue Task Force Litter with Tan Carrier |