TACTICAL MEDICAL SOLUTIONS, LLC

Declaration of Conformity

Manufacturer: **Tactical Medical Solutions, LLC**
1250 Harris Bridge Road - Anderson, SC 29621, U.S.A.

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)**

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

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 15223:2020	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

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Approval Date: 13 MAY 2021

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