

TACTICAL MEDICAL SOLUTIONS, LLC

Declaration of Conformity

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

Product: Tourniquets
Trademark(s):

- SOF® TACTICAL TOURNIQUET (SOF-T)
- SOF® TACTICAL TOURNIQUET WIDE (SOFTT-W)
- SOF® TACTICAL TOURNIQUET (SOFTT-NH)
- SOF® TACTICAL TOURNIQUET (SOFTT-XS)

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 TF003



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Approval Date: 13 MAY 2021



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