

TACTICAL MEDICAL SOLUTIONS, LLC

Declaration of Conformity

Manufacturer: Tactical Medical Solutions, LLC

Product: Control Wrap

Trademark(s):

- Control Wrap® (CW)

Classification: Class I – according to Annex IX

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

Main Directives: European Medical Device Regulation 2017/745
Standards: EN ISO 13485:2016 – Quality Management System
EN 1041:2008 (Amd A1:2013) – Information supplied by manufacturer
EN 15223:2020 – Medical devices – symbols for labelling
EN ISO 14971:2019 – Medical device risk management

EU Authorized Representative:

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Approval Date: 13 May 2021



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