



TACMED
SOLUTIONS

TACMED SOLUTIONS™, LLC

DECLARATION OF CONFORMITY

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

Product: Control Wrap®

Trademark(s):

- **Control Wrap® - 4 inch (Item Number: CW4)**
CW4 UDI: 818630010319
- **Control Wrap® - 6 inch (Item Number: CW6)**
CW6 UDI: 818630010326

TM

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:

CTC Medical GmbH,
Schönfelder Weg 23-31,
16321 Bernau bei Berlin
Germany
info@ctcmedical.de
Tel: +49 (0) 30 911 49 656

Technical File Number TF006

Alan Hester, Chief of Staff
TacMed Solutions™, LLC
Approval Date: 30 MAR 2022