



**TACMED
SOLUTIONS**

TACMED SOLUTIONS™, LLC

DECLARATION OF CONFORMITY

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

Product Trademarks: **OLAES® MODULAR BANDAGE** TM
 OAL-4 00818630010296
 OAL-6 00818630010302
 OALFP-4 00818630011682

BLAST® MODULAR BANDAGE
 BLAST 00818630010289

Classification: **Class I Sterilized– according to Annex IX Rule 4**
Conformity Assessment Route: **Annex V**

Hereby we declare that the above-mentioned product meets the provision of the stated EU Medical Device Directive 93/42/EEC 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:

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.
ISO 11137-1:2017 & ISO 11137-2: 2017	Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices
EN 1041:2008 + Amd A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 15223:2021	Medical Devices – Symbols to be used with information to be supplied by the manufacturer
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.
ISO 10993-1:2019 & EN ISO 10993-1:2019	Biological evaluation of medical devices – Evaluation and testing

Notified Body: NB1984	EU Authorized Representative:	
Kiwa - Belgelendirme Hiz. A.S. Eski Ankara Asfalti ITOSB 9. Cad. No: 15 Tepeoren Mevki Tuzla Istanbul, Turkey	CTC Medical GmbH, Schönfelder Weg 23-31, 16321 Bernau bei Berlin Germany info@ctcmedical.de Tel: +49 (0) 30 911 49 656	 Alan Hester, Chief of Staff TacMed Solutions™, LLC Approval Date, 09 MAY 2022
Technical File Number:	TF001	