TACMED SOLUTIONS™, LLC

DECLARATION OF CONFORMITY

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

Product: **HELIOS**
Trademark(s):

Product Description	Part Number	UDI
HELIOS System	HELIOS-K	818630010456
HELIOS System Active Warming	HELIOS-KW	818630010463

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:

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Technical File Number TF006

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TacMed Solutions™, LLC
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