



EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
TechTrade LLC	6900 Tavistock Lakes Blvd. Suite 400 Orlando, FL 32827 USA	US-MF-000023808

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
Ready-Heat One Panel Blanket	S1RHSM
Ready-Heat Four Panel Blanket	S4RHMD/S4RHMD-N
Ready-Heat Six Panel Blanket	S6RHLG
Ready-Heat Vest	GRHV06A
Ready-Heat Infant Warming Blanket	GIW6C
Ready-Heat II Blanket	G12RH2
Ready-Heat Temperature Management Full Body	SB9RH9120
Ready-Heat Infant Warming Mattress	S2RHIM
Ready-Heat II Torso Blanket	G6RH2T/G6RH2TB
Ready-Heat Temperature Management Half Body	SB6RH9120
Ready-Heat Emergency and Disaster Blanket	ED9RH
Intended Purpose	Basic UDI-DI
To provide warm relief, aid in the prevention of hypothermia	0850017905100SB
CDN/EMDN Description and Code: Body Thermoregulation Equipment – Z12040208	

RISK CLASS FOR DEVICES		
Device Classification		Common Specifications / Standards
Class:	Ila	
Rule:	9	
		Technical File Information
		TF-01 Rev S Dec 2025

NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
GMED SAS	CE0459	Annex II excluding section 4 of MDD 93/42/EEC Council Directive	36083 rev.2, Add. 38580 rev.7, Conf. Letter 39487 rev.0



TechTrade LLC., hereby declares under our exclusive responsibility the above-mentioned products meet the relevant provisions of the **Medical Device Directive (MDD) 93/42/EEC and Medical Devices Regulation (MDR) (EU) 2017/745 Article 120 Transitional Provisions and those General Safety and Performance Requirements listed in Annex I**; also, any applicable standards, any Common Specifications, or related European Union legislation. The conformity of the device is confirmed through placement of the CE Mark on each device. All supporting documentation is retained under the premises of the manufacturer.

List of Harmonized Standards, Common Specifications, and other relevant EU legislation

Identification Number	Title or Description	Version or Year
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	2016
MDD 93/42/EEC	Medical Device Directive 93/42/EEC (EU)	2007
MDR EU 2017-745	European Regulation (EU) 2017/745 for Medical Devices	2017
EN ISO 14971 +A11	Medical devices — Application of risk management to medical devices	2019 2021
EN 62366-1 + AMD1	Medical devices. Application of usability engineering to medical devices	2015 2020
EN ISO 15223-1/AMD 1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	2021/2025
(EU) 2021/2226 + AMD 2025/1234	Medical Devices - Rules for implementing EU Regulation for which the instructions for use may be provided in electronic form	2021/2025
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2026
ISO 20417	Information Supplied by the Manufacturer	2026
Regulation (EU) 2025/40	Packaging and Packaging Waste Regulation (PPWR) – applicable packaging obligations and healthcare derogations addressed per TechTrade PPWR Packaging Statement dated 10 August 2026	2025

COMPANY REPRESENTATIVE: Erin Bart

TITLE: Regulatory Manager/PRRC

SIGNATURE: 

PLACE: Orlando, FL, USA

DATE: EU 10/8/2026

TechTrade, LLC
Tax ID 45-0507628
OFFICIAL DOCUMENT



REV STATUS:

Revision	Date Issued	Revision History
13	5/13/2021	Current Rev
14	6/14/2021	Updated certificate number to 36083 rev 2
15	3/24/2022	Added AR SRN, Article 120 provisions, updated company address
16	5/24/2022	Added TechTrade SRN, Updated TF reference, Added product code S4RHMD-N
17	6/24/2022	Added Basic UDI-DI number, Updated certificate numbers (added addendum to cert 38580 rev 3)
18	1/31/2023	Added CDN/EMDN Description, Updated AR address and email, Updated TF reference, added declaration with standards, updated add. Rev to 4
19	5/24/2023	Updated addendum rev to 5, added GSPR to declaration
20	1/31/2024	Updated TF reference, added Confirmation Letter 39487 rev 0 to certs
21	2/5/2025	Updated TF reference, removed EU 207/2012 standard from declaration as it was NA
22	7/21/2025	Updated CE certificate addendum to Rev 6
23	5/18/2026	Updated CE certificate addendum to Rev 7, Updated ISO 15223-1 to include addendum, Updated ISO 20417 and ISO 10993 to 2026 revs, Added (EU) 2021/2226 + AMD 2025/1234
24	8/10/2026	Added Regulation (EU) 2025/40 (PPWR) to relevant EU legislation; issued separate PPWR Packaging Statement