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**	**Technical File Information**
Class:	IIa		TF-01 Rev P Jan 2023
Rule:	9		

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
GMED SAS	CE0495	Annex II excluding section 4 of MDD 93/42/EEC Council Directive	36083 rev.2, Add. 38580 rev.4

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	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	2021
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2020
EU 207/2012	Regulation (EU) No 207/2012 on electronic instructions for use of medical devices	2012
ISO 20417	Information Supplied by the Manufacturer.	2021

COMPANY REPRESENTATIVE: Erin Bart

TITLE: Regulatory Manager/PRRC **SIGNATURE:**

PLACE: Orlando, FL, USA **DATE:** EU 31/01/2023