

## Manufacturer's EU Declaration of Conformity

**Manufacturer:** Water-Jel Technologies, LLC

**Address:** 50 Broad Street  
Carlstadt, NJ 07072 USA

**Authorized Rep:** Safeguard Technologies Ltd.  
Willow Grove  
Delgany, Co Wocklow  
A63 XY89  
Ireland

Water-Jel Technologies, LLC declares that the below mentioned medical device(s) comply with the provision of the EC Directive 93/42/EEC as amended by EC Directive 2007/47/EC which apply to it based on its intended use under the supervision of BSI, a Notified Body duly authorized by EU Competent Authority to carry out such assessments and carrying the Notified Body Number 2797.

According to **Annex IX** of the Directive 93/42/EEC as amended, rule 4, the device(s) are classified as

### **Class IIb – non-sterile, non-invasive medical device**

This declaration is based on **Annex II** (excluding Section 4) of **EC Directive 93/42/EEC** as amended.

Certification of a quality system according to:

Directive 93/42/EEC, Annex II (excluding Section 4) and amending directive **2007/47/EC** – Certificate Number **CE 554803**

**ISO 13485:2016** – Certificate Number: **FM 702917**

The listed medical device(s), their design, manufacturing, distribution comply with the following harmonized standards:

- EN ISO 13485 Medical Device – Quality Management Systems
- EN ISO 14971 Medical Device – Application of risk management
- ISO 15223-1 Medical Device – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

This declaration of conformity is issued under the sole responsibility of Water-Jel Technologies, LLC.

*Kimberly Reed*

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Kimberly Reed  
Global Director of Regulatory Affairs

05/16/23

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Date



**Attachment 1: List of Products**

<b>Product Description</b>	<b>Product Code</b>	<b>Case Pack</b>
BurnFree 91cm x 76cm (36" x 30") Fire/Trauma Blanket w/ Water-Resistant carrying case	#SB-9176	1 Blanket each carrier bag
BurnFree 183cm x 152cm (72" x 60") Fire/Trauma Blanket w/ Water-Resistant carrying case	#SB-183152	1 Blanket each carrier bag
BurnFree 244cm x 152cm (96" x 60") Fire/Trauma Blanket w/ Water-Resistant carrying case	#SB-244152	1 Blanket each carrier bag
BurnFree 91cm x 76cm (36" x 30") Fire/Trauma Blanket w/ Waterproof carrying case	#SBM-9176	1 Blanket each carrier bag
BurnFree 183cm x 152cm (72" x 60") Fire/Trauma Blanket w/ Waterproof carrying case	#SBM-183152	1 Blanket each carrier bag
BurnFree 244cm x 152cm (96" x 60") Fire/Trauma Blanket w/ Waterproof carrying case	#SBM-244152	1 Blanket each carrier bag






# Declaration of Conformity - BurnFree Blankets May 2023

Final Audit Report

2023-05-16

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