

## 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 – sterile and non-sterile, non-invasive medical devices**

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.

DocuSigned by:  
*Kimberly Reed*  
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13-Sep-2023

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Kimberly Reed  
Global Director of Regulatory Affairs

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Date





HEALTHCARE BEYOND BURN CARE

**Attachment 1: List of Products**

<b>Product Description</b>	<b>Product Code</b>	<b>Risk Classification</b>
Dressing 5 x 15 cm, 15 pcs	B0206	IIb
Dressing 10 x 10 cm, 15 pcs	B0404	IIb
Dressing 10 x 40 cm. 7 pcs	B0416	IIb
Dressing 20 x 45 cm. 5 pcs	B0818	IIb
Hand Dressing 20 x 55 cm, 5 pcs	B0820	IIb
Face Mask 30 x 40 cm, 5 pcs	B1216	IIb
Blankets, Burn Wrap 91 x 76 cm, 1 pc	G3630P	IIb
Blankets, Burn Wrap Canister 91 x 76 cm, 1 pc	G3630C	IIb
Blankets, Fire Blanket Plus 183 x 152 cm, 1 pc	G7260P	IIb
Blankets, Fire Blanket Plus Canister 183 x 152 cm, 1 pc	G7260C	IIb
Blanket Heat Shield Canister 244 x 183 cm, 1 pc	G9672C	IIb
Tactical Dressing 10 x 10 cm	WJ10HA	IIb
Tactical Dressing 10 x 40 cm	WJ30HA	IIb
Tactical Dressing 20 x 45 cm	WJ50HA	IIb
Universal Dressing	WJ70HA	IIb
Tactical Blankets Canister 91 x 76 cm	3630-MC	IIb
Tactical Blankets Pouch 183 x 152 cm	7260-MC	IIb

End of list