

## 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



HEALTHCARE BEYOND BURN CARE

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>
Burn Jel HA 240 ml bottles	GBJ240	IIb
Burn Jel HA 340 ml bottles	GBJ340	IIb
Burn Jel HA 640 ml bottles	GBJ640	IIb
Burn Jel HA 80 ml bottles	GBJ80	IIb
Burn Jel EU HA 120ml bottles	GBJ120	IIb
Burn Jel EU HA 50ml bottles	GBJ50	IIb
Burn Jel HA 4.0g Unit Dose	GBJ140	IIb

End of list