WATERJEL® TECHNOLOGIES
HEALTHCARE BEYOND BURN CARE

DECLARATION OF CONFORMITY

I, **Kimberly Reed**, hereby declare that the below mentioned medical device(s)

To which the declaration relates, and which bear the CE Marking, are in conformity with the applicable requirements of EC Directive 93/42EEC as amended by 2007/47/EC.

(A) Particulars of Medical Device

Manufacturer: Water-Jel Technologies, LLC.
Country of Origin: United States
Manufacturing Site: 50 Broad Street, Carlstadt, NJ 07072, USA
Risk-based Classification: IIB
Classification Rule: 4
European Authorized Representative:

Safeguard Technologies Ltd., Willow Grove, Delgany, Co Wicklow, A63 XY89, Ireland

Medical device registration number /approval code:

No	Regulatory Body	Approval Code/Registration Number
1	BSI 2797	CE 554803

(B) Quality Management System (QMS) certificate(s):

Conformity Assessment Body issuing the certificate: ISO 13485:2016
Certificate Number: FM 702917
Issuance Date: 07/27/2009
Expiry Date: 03/01/2025

(C) Standards Applied:

We hold:

- MDD 93/42/EEC:2007 on (Medical Device Directive) Annex II, excluding Section 4.
- ISO13485:2016 Medical devices quality management systems requirement for regulatory purposes.

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We comply with:

- ISO14971:2007 Medical devices – Application of risk management to medical devices.
- ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

I am responsible the information provided in this declaration. I fully understand and acknowledge that it is an offense under section 76 of the Medical Device Act 2012 (Act 737) to make, sign, or furnish any declaration, certificate, or other document which is untrue, inaccurate, or misleading.

Authorised Signatory:

Kimberly Reed

Kimberly Reed
Global Director of Regulatory Affairs

Date: 16 December 2022



50 Broad Street ■ Carlstadt, New Jersey 07072 ■ Tel: 201-507-8300
Fax: 201-507-8325 ■ email: info@waterjel.com ■ www.waterjel.com

HEALTHCARE BEYOND BURN CARE

Attachment 1: List of Products

Product Description	Product Code	Risk Classification
Burn Jel HA 240 ml bottles	GBJ240	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 3 x 4g sachets	GBJ340	IIb
Burn Jel HA 6 x 4g sachets	GBJ640	IIb
Burn Jel HA 4.0g Unit Dose	GBJ140	IIb

End of list

Declaration_of_Conformity Gels Rev2b 121622

Final Audit Report 2022-12-16

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