WATER-JEL® 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. – A Safeguard Medical Company
Country of Origin: United States
Manufacturing Site: 50 Broad Street, Carlstadt, NJ 07072, USA
Risk-based Classification: IIB
Classification Rule: 4
Legal European Importer:

Safeguard International, 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:

- MDD93/42/EEC:2007 European League medical device instructors
- ISO13485:2016 Medical devices quality management systems requirement for regulatory purposes.

We comply with:

- ISO14971:2007 Medical devices – Application of risk management to medical devices.
- ISO11607-1:2019 Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

WATER-JEL® TECHNOLOGIES

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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: September 09, 2022

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

WATERJEL® TECHNOLOGIES

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Attachment 1: List of Products

Product Description	Product Code	Risk Classification
Dressing 5 x 15 cm, 15 pcs	80206	IIb
Dressing 10 x 10 cm, 15 pcs	80404	IIb
Dressing 10 x 40 cm. 7 ocs	B0416	IIb
Dressing 20 x 45 cm. 5 ocs	B0818	IIb
Hand Dressing 20 x 55 cm, 5 pcs	80820	IIb
Face Mask 30 x 40 cm, 5 pcs	81216	IIb
Blankets, Burn Wrap 91 x 76 cm, 1 pc	GP3630	IIb
Blankets, Burn Wrap Canister 91 x 76 cm, 1 pc	G3630	IIb
Blankets, Fire Blanket Plus 183 x 152 cm, 1 pc	GP7260	IIb
Blankets, Fire Blanket Plus Canister 183 x 152 cm, 1 pc	G7260	IIb
Blanket Heat Shield Canister 244 x 183 cm, 1 pc	G9672	IIb
Tactical Dressinas 10 x 1o cm	WJ10HA	IIb
Tactical Dressinas 10 x 40 cm	WJ30HA	IIb
Tactical Dressinas 20 x 45 cm	WJS0HA	IIb
Universal Dressina	WJ70HA	IIb
Tactical Blankets Canister 91 x 76 cm	3630-MIL	IIb
Tactical Blankets Pouch 183 x 152 cm	7260-Mll-P	IIb
Tactical Blankets Canister 183 x 152 cm	7260-MIL	IIb

End of list

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Authorised Signatory:

Kimberly Reed

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Kimberly Reed
Global Director of Regulatory Affairs

Date: September 09, 2022

WATER-JEL TECHNOLOGIES LLC CORPORATE SEAL 2016 NEW JERSEY

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WATERJEL® TECHNOLOGIES

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 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 60ml bottles	BJEU2-48	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
Burn Stop 50ml Gel for WJE	BSG50G	IIb
Burn Stop 1728 pcs/case Unit dose	BSG350R	IIb
BurnFree SD, 3.5g 1,000 pcs/case	#SDI1000	IIb
BurnFree SD, 3.5g 6pcs/bx-100bx/case	#SD6-100	IIb
BurnFree SD, 3.5g 25pcs/bx-24bx/case	#SD25-24	IIb
BurnFree 20, 3.5g 20 pcs/bx-30bx/case	#SD20-30	IIb
BurnFree 60ml 48 pcs/case	#60B48	IIb
BurnFree 120ml 24 pcs/case	#120B24	IIb

End of list

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Declaration of Conformity - BD Gel HA - Blankets Dressings Gels (090822)

Final Audit Report 2022-09-13

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"Declaration of Conformity - BD Gel HA - Blankets Dressings Gels (090822)" History

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