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

Generic Name: BurnFree Sterile Burn and Wound Dressings
Specified Name: BurnFree Sterile Burn and Wound Dressings
Brand/Model: BurnFree
Manufacturer: Water-Jel Technologies, LLC. – A Safeguard Medical Company
Country of Origin: United States
Manufacturing Site: 50 Broad Street, Carlstadt, NJ 07072, United States
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: ISO13485:2016
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

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

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Kimberly Reed
Global Director of Regulatory Affairs

Date: August 18, 2022

WATER-JEL TECHNOLOGIES LLC CORPORATE SEAL 2016 NEW JERSEY

Attachment 1: List of Products

Product Description	Individual Pack	Product Code	Case Pack	Product Code
BurnFree 5cm x 5cm (2"x 2") Sterile Burn Dressing	1 Dressing	#0505	120 Dressings	#0505120.00.000
BurnFree 5cm x 5cm (2"x 2") Sterile Burn Dressing	1 Dressing	#0505	400 Dressings	#0505400.00.000
BurnFree 5cm x 15cm (2"x 6") Sterile Burn Dressing	1 Dressing	#0515	60 Dressings	#051560.00.000
BurnFree 5cm x 15cm (2"x 6") Sterile Burn Dressing	1 Dressing	#0515	250 Dressings	#0515250.00.000
BurnFree 10cm x 10cm (4"x 4") Sterile Burn Dressing	1 Dressing	#1010	60 Dressings	#101060.00.000
BurnFree 10cm x 10cm (4"x 4") Sterile Burn Dressing	1 Dressing	#1010	150 Dressings	#1010150.00.000
BurnFree 10cm x 40cm (4"x 16") Sterile Burn Dressing	1 Dressing	#1040	20 Dressings	#104020.00.000
BurnFree 20cm x 20cm (8"x 8") Sterile Burn Dressing	1 Dressing	#2020	30 Dressings	#202030.00.000
BurnFree 20cm x 45cm (8"x 18") Sterile Burn Dressing	1 Dressing	#2045	20 Dressings	#0505120.00.000
BurnFree 30cm x 30cm (12"x 12") Sterile Burn Dressing	1 Dressing	#3030	20 Dressings	#303020.00.000
BurnFree 30cm x 40cm (12"x 16") Sterile Face Mask Burn Dressing	1 Dressing	#3040	20 Dressings	#304020.00.000

Declaration of Conformity - BurnFree Dressings (081822)

Final Audit Report 2022-08-18

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