

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
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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, 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 11607-1 Packaging for terminally Sterilized Medical Devices Part 1
- 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.

Kimberly Reed

Kimberly Reed
Global Director of Regulatory Affairs

05/19/23

Date



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	#0505-120
BurnFree 5cm x 5cm (2"x 2") Sterile Burn Dressing	1 Dressing	#0505	400 Dressings	#0505-400
BurnFree 5cm x 15cm (2"x 6") Sterile Burn Dressing	1 Dressing	#0515	60 Dressings	#0515-60
BurnFree 5cm x 15cm (2"x 6") Sterile Burn Dressing	1 Dressing	#0515	250 Dressings	#0515-250
BurnFree 10cm x 10cm (4"x 4") Sterile Burn Dressing	1 Dressing	#1010	60 Dressings	#1010-60
BurnFree 10cm x 10cm (4"x 4") Sterile Burn Dressing	1 Dressing	#1010	150 Dressings	#1010-150
BurnFree 10cm x 40cm (4"x 16") Sterile Burn Dressing	1 Dressing	#1040	20 Dressings	#1040-20
BurnFree 20cm x 20cm (8"x 8") Sterile Burn Dressing	1 Dressing	#2020	30 Dressings	#2020-30
BurnFree 20cm x 45cm (8"x 18") Sterile Burn Dressing	1 Dressing	#2045	20 Dressings	#2045-20
BurnFree 30cm x 30cm (12"x 12") Sterile Burn Dressing	1 Dressing	#3030	20 Dressings	#3030-20
BurnFree 30cm x 40cm (12"x 16") Sterile Face Mask Burn Dressing	1 Dressing	#3040	20 Dressings	#3040-20






Declaration of Conformity - BurnFree Dressings May 2023

Final Audit Report

2023-05-19

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