

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 – 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

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 60ml (2oz) Pain Relieving Gel - Squeeze Bottle	1 bottle	#60B	48 Bottles	#60B-48
BurnFree 120ml (4oz) Pain Relieving Gel - Squeeze Bottle	1 bottle	#120B	24 Bottles	#120B-24
BurnFree 3.5gm (1/8oz) Single Dose Pain Relieving Gel Sachet – Bulk Pack	1 sachet	#SD135	1000 Sachets	#SDI-1000
BurnFree 3.5gm (1/8oz) Single Dose Pain Relieving Gel Sachet – 20 pack	1 Folding Carton x 20 sachets	#SD20	30 Folding carton each case	#SD20-30






Declaration of Conformity - BurnFree Gels May 2023

Final Audit Report

2023-05-19

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