



DECLARATION OF CONFORMITY

I, **Sandra Salazar**, 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 Pain Relieving Gel
Specified Name: BurnFree Pain Relieving Gel
Brand/Model: BurnFree
Manufacturer: Water-Jel Technologies, Inc. – 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	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: 03/01/2022

(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. ully 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:

Sandra Salazar

Sandra Salazar
Quality Assurance and Compliance Manager

Date: July 14, 2021





Attachment 1: List of Products

Product Description	Product Code	Case Pack
BurnFree 60ml (2oz) Pain Relieving Gel - Squeeze Bottle	#60B / #2BD	48 Bottles
BurnFree 120ml (4oz) Pain Relieving Gel - Squeeze Bottle	#120B / #4BD	24 Bottles
BurnFree 3.5gm (1/8oz) Single Dose Pain Relieving Gel Sachet – Bulk Pack	#SD135	1000 sachets
BurnFree 3.5gm (1/8oz) Single Dose Pain Relieving Gel Sachet – 20 pack	#SD135/#SD20	30 boxes/20 sachets each box