



## 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

**Country of Origin:** United States

**Manufacturing Site:** 50 Broad Street, Carlstadt, NJ 07072, USA

**Risk-based Classification:** IIB

**Classification Rule:** 4

**European Authorized Representative:**

Safeguard Technologies 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:

- MDD 93/42/EEC:2007 on (Medical Device Directive) Annex II, excluding Section 4.
- 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



**HEALTHCARE BEYOND BURN CARE**

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:

DocuSigned by:  
*Kimberly Reed*  
7C1258B50D44474...

Kimberly Reed  
Global Director of Regulatory Affairs

Date: 9 December 2022





**HEALTHCARE BEYOND BURN CARE**

**Attachment 1: List of Products**

| <b>Product Description</b>                              | <b>Product Code</b> | <b>Risk Classification</b> |
|---------------------------------------------------------|---------------------|----------------------------|
| Dressing 5 x 15 cm, 15 pcs                              | B0206               | IIb                        |
| Dressing 10 x 10 cm, 15 pcs                             | B0404               | IIb                        |
| Dressing 10 x 40 cm. 7 pcs                              | B0416               | IIb                        |
| Dressing 20 x 45 cm. 5 pcs                              | B0818               | IIb                        |
| Hand Dressing 20 x 55 cm, 5 pcs                         | B0820               | IIb                        |
| Face Mask 30 x 40 cm, 5 pcs                             | B1216               | IIb                        |
| Blankets, Burn Wrap 91 x 76 cm, 1 pc                    | G3630P              | IIb                        |
| Blankets, Burn Wrap Canister 91 x 76 cm, 1 pc           | G3630C              | IIb                        |
| Blankets, Fire Blanket Plus 183 x 152 cm, 1 pc          | G7260P              | IIb                        |
| Blankets, Fire Blanket Plus Canister 183 x 152 cm, 1 pc | G7260C              | IIb                        |
| Blanket Heat Shield Canister 244 x 183 cm, 1 pc         | G9672C              | IIb                        |
| Tactical Dressing 10 x 10 cm                            | WJ10HA              | IIb                        |
| Tactical Dressing 10 x 40 cm                            | WJ30HA              | IIb                        |
| Tactical Dressing 20 x 45 cm                            | WJ50HA              | IIb                        |
| Universal Dressing                                      | WJ70HA              | IIb                        |
| Tactical Blankets Canister 91 x 76 cm                   | 3630-MC             | IIb                        |
| Tactical Blankets Pouch 183 x 152 cm                    | 7260-MC             | IIb                        |

End of list

**Certificate Of Completion**

Envelope Id: 58E1989F0DB54B6D88E09CD1A8FA0C89 Status: Completed  
 Subject: Complete with DocuSign: Declaration of Conformity - BD Gel HA - Blankets Dressings Rev 2c.docx  
 Source Envelope:  
 Document Pages: 3 Signatures: 1 Envelope Originator:  
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 Global Director, Regulatory Affairs  
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