

EC Declaration of Conformity

Products covered in this Declaration of Conformity are detailed below.

These products are intended to be used for emergency first aid for treatment of burn injuries.

Manufacturer:

Water-Jel Technologies LLC,
50 Broad Street,
Carlstadt, NJ 07072
USA

European Authorized Representative:

Safeguard Technologies Ltd, Willow Grove, Delgany, Co Wicklow, A63 XY89, Ireland

Declaration:

Water-Jel Technologies LLC US, declares under its sole responsibility that the products detailed below 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.

Conformity assessment procedure for CE marking:

Risk Class IIb, Medical Device Directive, Annex II

Notified Body / Certificate Reference:

BSI (NB#2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

EC Certificate CE 554803 first issued 2010-04-22

Name, Function and signature of manufacturer:

Sandra Salazar

January 27, 2022

Sandra Salazar
Sr. Manager Quality Assurance and Compliance
Water-Jel Technologies LLC

Date

Product Type, Code & Listing

Product Description	Product Code	Risk Classification
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	GP3630	IIb
Blankets, Burn Wrap Canister 91 x 76 cm, 1 pc	G3630	IIb
Blankets, Fire Blanket Plus 183 x 152 cm, 1 pc	GP7260	IIb
Blankets, Fire Blanket Plus Canister 183 x 152 cm, 1 pc	G7260	IIb
Blanket Heat Shield Canister 244 x 183 cm, 1 pc	G9672	IIb
Tactical Dressings 10 x 10 cm	WJ10HA	IIb
Tactical Dressings 10 x 40 cm	WJ30HA	IIb
Tactical Dressings 20 x 45 cm	WJ50HA	IIb
Universal Dressing	WJ70HA	IIb
Tactical Blankets Canister 91 x 76 cm	3630-MIL	IIb
Tactical Blankets Pouch 183 x 152 cm	7260-MIL-P	IIb
Tactical Blankets Canister 183 x 152 cm	7260-MIL	IIb

End of list