

Manufacturer's EC Declaration of Conformity

Manufacturer: Blizzard Protection System Ltd.
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declares and guarantees the product

Product Name:	Hypothermia Protection
Intended Use:	For the prevention & treatment of hypothermia.
Product Code/Number:	See Annex I
Basic UDI	506029721BPSRangeBC

complies with 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.

According to the **Annex IX** of the **Council Directive 93/42/EEC, rule 1**, the product is classified as

Class I, Rule 1 – non - sterile, non-invasive medical device

The appropriate registration has been made to MHRA as the competent authority in the UK.

Blizzard Protection System Ltd. agrees to develop, implement and maintain the post-production experience monitoring process, including the notification of reportable events under the European Medical Vigilance System Guidelines.

This declaration is based on the **Annex VII** of **EC Directive 93/42/EEC**.

The listed medical device, its design, manufacturing, distribution complies with the following harmonized standards:

UK MDR 2002	Medical Devices Regulation 2002
EN ISO 9001:2015	Medical Device – Quality Management Systems - Requirements
EN ISO 14971:2019	Medical Device – Application of risk management to medical devices
EN ISO 31000:2018	Risk Management Principles and Guidelines

- EN ISO 31010:2019 Risk Management: Risk Assessment Techniques
- EN ISO 20417:2021 Medical Devices - Information to be supplied by the manufacturer
- EN ISO 15223-1:2021 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied
- EN ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 62366-1:2015 Medical Devices - Part 1: Application of usability engineering to medical devices

This declaration of conformity is issued under the sole responsibility of Blizzard Protection System Ltd. as the Legal Manufacturer of the Product.

Signed *Eva Havelkova* Date: 12.06.2023 Place: Gwynedd

Eva Havelková - Director of International Quality and Regulatory Compliance

Version Number	2
Issue Date	12/06/2023
Change Number	08_23

Version History

DC Number	Version	Date	Description of Change
08_22	1	31.10.2022	First issue of document
08_23	2	12.06.2023	Document updated for new part numbers: BPS-65(FP), BPS-66(VB) and part numbers BPS-10 (FP),RE BPS-24S were removed.

Annex 1: List of products

BPS Code	Product Name
BPS-01	Blizzard Trauma Blanket
BPS-10	Blizzard Trauma Blanket
BPS-33	Blizzard AMB Trauma Blanket
BPS-34	Blizzard AMB Trauma Blanket
BH-07	Blizzard Casualty Trauma Blanket XL
BH-09	Blizzard Casualty Trauma Blanket XL
BSPR-01	Blizzard Casualty Trauma Blanket
BSPR-03	Blizzard Casualty Trauma Blanket
BPS-44(FP)	Blizzard Trauma Blanket with Hook & Loop Closure
BPS-44(VB)	Blizzard Trauma Blanket with Hook & Loop Closure
BPS2-370	Blizzard Compact Trauma Blanket
BPS2-10 (VB)	Blizzard EMS Trauma Blanket
BPS2-10 (FP)	Blizzard EMS Trauma Blanket
BPS2-01 (VB)	Blizzard EMS Trauma Blanket
BPS2-01 (FP)	Blizzard EMS Trauma Blanket
BPS-01S	Blizzard Survival Blanket. (Slim)
BPS-10S	Blizzard Survival Blanket. (Slim)
BPS-02	Blizzard Survival Bag
BPS-11	Blizzard Survival Bag
BPS-03	Blizzard Survival Jacket
BPS-12	Blizzard Survival Jacket
BPS-19	Blizzard Rescue Jacket (Long)
BPS-15	Blizzard Rescue Jacket (Long)

BPS-23	Blizzard Baby Wrap
BPS-24	Blizzard Adult Beanie Hat
BPSAR-10	Blizzard Active Range Blanket
BPSAR-11	Blizzard Active Range Bag
BPSAR-12	Blizzard Active Range Jacket
BPS47	Blizzard IFAK Blanket
BPS-65 (FP)	Blizzard Trauma Blanket with Hook & Loop Closure
BPS-66 (VB)	Blizzard Trauma Blanket with Hook & Loop Closure






Annex 01.3 BDQ037_UK DofC_Hypothermia Products_V2

Final Audit Report

2023-06-14

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