

Manufacturer's EU 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 **MDR 2017/745** which apply to it based on its intended use.

According to the **Annex VIII** of the **MDR 2017/745**, **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 England, and the base for the Blizzard Authorised Representative in the EU.

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 IV** of **MDR 2017/745**.

The following standards, regulations, guidelines, and state of the art documents have been adhered to by Blizzard in order to demonstrate compliance of the product with the **Regulation (EU) on Medical Devices 2017/745**:

Regulations and Guidelines	Description
GHTF/SG1/N68:2012	Essential Principles of Safety and Performance of Medical Devices
GHTF/SG1/N70:2011	Label and Instructions for Use for Medical Devices
GHTF/SG1/N77/N15:2012	Principles of Medical Device Classification
EU MDR 2017/745	EU Regulations for Medical Devices
MEDDEV 2.7/1_Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/2_Rev 2	Post-Market Clinical Follow-Up Studies
MEDDEV 2.12-1_Rev 8	Medical Device Vigilance System
MDCG 2020-6	Guidance on Sufficient Clinical Evidence for Legacy Devices
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template
MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

State of the Art	Description
EN ISO 9001:2015	Quality Management Systems - Requirements
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 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

Harmonised Standards with Regulation (EU) 2017/745 on Medical Devices	Description
ISO 15223-1:2021	Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management 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	09_23

Version History

DC Number	Version	Date	Description of Change
07_22	1	31.10.2022	First issue of document
09_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 01.4_BDQ038_EU DofC_Hypothermia Products_V2

Final Audit Report

2023-06-14

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