
	<b>EU Declaration of Conformity</b>	TF-84
	Emergency Blanket (Foil Blanket)	
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## Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

This EU declaration of conformity is issued under the sole responsibility of the manufacturer to state that the requirements specified in Regulation (EU) 2017/745, and other applicable Union legislation as listed in Annex 1 to this declaration, have been fulfilled in relation to the devices listed in Annex 4 to this declaration.

<b>Name and address of Manufacturer:</b>	Crest Medical Limited. Unit 5 Farrell Industrial Estate, Howley Lane, Warrington WA1 2PB, UK		
<b>Single Registration Number (SRN):</b>	GB-MF-000025649		
<b>Basic UDI-DI:</b>	5039139C1NTF84FU		
<b>Product Name:</b>	Emergency Blanket (Foil Blanket)		
<b>Product Codes or Catalogue Numbers:</b>	As per Annex 4 – Device Listing		
<b>Intended Purpose:</b>	Emergency blanket is used in emergencies to reduce heat loss in a person's body caused by thermal radiation, water evaporation and convection and to keep patient warm.		
<b>GMDN Code:</b>	66298	<b>EMDN Code:</b>	V9099
<b>Risk Class:</b>	Class I	<b>Classification Rules:</b>	Rule 1
<b>Sterile:</b>	No	<b>Measuring Function:</b>	No
		<b>Reusable Surgical Inst.:</b>	No
<b>Common Specifications (CS):</b>	As per Annex 2 – Common specifications See also: Annex 3 Applicable Standards		
<b>Notified Body:</b>	N/A		
<b>Conformity Assessment Procedure:</b>	Article 52(7)		
<b>Certificate Type(s) and Reference Number(s):</b>	ISO 13485 Certificate: GB98/12980		
<b>EU Authorised Representative:</b>	CMC Medical Devices& Drugs S.L C/Horacio Lengo N 18, CP29006, Málaga-Spain		
<b>Additional Information:</b>	None		

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**Declaration Signature:**


Date: 16 December 2025

Location: As above

Name: Matthew Courtney

Position: Director and person responsible for regulatory compliance of the manufacturer.

Signed:  \_\_\_\_\_

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### ANNEX 1 – Union legislation

The devices listed in Annex 4 are in conformity with the following Union legislation:

- Regulation (EU) 2017/745

### ANNEX 2 – Common Specifications (CS)

There are currently no CS's which apply to these devices.

### ANNEX 3 – Applicable Standards

Standard Ref.	Standard title
ISO 13485	Medical Devices – Quality Management Systems –Requirements for regulatory purposes.
EN ISO 14971	Medical devices. Application of risk management to medical devices
EN 1041	Harmonised standard. Information Supplied by the Manufacturer of Medical Devices
EN ISO 15233-1	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN 62366-1	Medical Devices – Application of usability in engineering to medical devices.
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system process.
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity
EN ISO 10993-10	Biological evaluation of medical devices – Tests for skin sensitization
EN ISO 10993-23	Biological evaluation of medical devices – Tests for irritation

### ANNEX 4 – Device Listing

Product Code / Catalogue No.	Device Description/Name
30BDFB18	Blue Dot Emergency Thermal Blanket 204cm x 140cm
30BDFB19	Blue Dot Child Emergency Thermal Blanket 120cm x 90cm
BP30BDFB18	Boots Heat Retaining Foil Blanket 204cm x 140cm
91004	Medikit Foil Blanket 204cm x 140cm
4803013	Astroplast Foil Blanket 130cm x 210cm
4803009	Astroplast Foil Blanket 160cm x 210cm
F18017	St John Ambulance Heat Retaining Blanket Adult 204 cm x 140cm
4803009S	Wallace Cameron Sustainable Thermal Blanket 140cm x 204cm (Each)