
	EU Declaration of Conformity	TF-022
	Non-Sterile Bandages	
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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.

Name and address of Manufacturer:	Crest Medical Limited. Unit 5 Farrell Industrial Estate, Howley Lane, Warrington WA1 2PB, UK				
Single Registration Number (SRN):	GB-MF-000025649				
Basic UDI-DI:	5039139C1NTF22F6				
Product Name:	Non sterile bandages				
Product Codes or Catalogue Numbers:	As per Annex 4 – Device Listing				
Intended Purpose:	Re-useable BP Crepe Bandage & Crepe Bandage for use as compression (light) support of injured or weakened limbs. Single Use Conforming (Stretch) Bandage for securing dressings or protecting delicate skin. Training Dressing – Unsterile dressing – to be used for training only.				
GMDN Code:	58964	EMDN Code:	M0304		
Risk Class:	Class I	Classification Rules:	Rule 1 (Self Certified)		
Sterile:	No	Measuring Function:	No	Reusable Surgical Inst.:	No
Common Specifications (CS):	As per Annex 2 – Common specifications See also: Annex 3 Applicable Standards				
Notified Body:	N/A				
Conformity Assessment Procedure:	Article 52(7)				
Certificate Type(s) and Reference Number(s):	ISO 13485 Certificate: GB98/12980				
EU Authorised Representative:	CMC Medical Devices& Drugs S.L C/Horacio Lengo N 18, CP29006, Málaga-Spain				
Additional Information:	None				

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Declaration Signature:

Date: 20 November 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 10993-10	Biological evaluation of medical devices – Tests for skin irritation
EN ISO 10993-12	Biological evaluation of medical devices – Part 12: Sample Preparation & Reference Materials

ANNEX 4 – Device Listing

Product Code / Catalogue No.	Device Description/Name
30BDCR05	Blue Dot Crepe Bandage 5cm x 4.5m
30BDCR05-10	Blue Dot Crepe Bandage 5cm x 4.5m
30BDCR75	Blue Dot Crepe Bandage 7.5cm x 4.5m
30BDCR75-10	Blue Dot Crepe Bandage 7.5cm x 4.5m
30BDCR10	Blue Dot Crepe Bandage 10cm x 4.5m
30BDCR10-10	Blue Dot Crepe Bandage 10cm x 4.5m
30BDCR15	Blue Dot Crepe Bandage 15cm x 4.5m

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30BDCR15-10	Blue Dot Crepe Bandage 15cm x 4.5m
30BDC005	Blue Dot Conforming Bandage 5cm x 4.5m
30BDC005-10	Blue Dot Conforming Bandage 5cm x 4.5m
30BDC075	Blue Dot Conforming 7.5cm x 4.5m
30BDC075-10	Blue Dot Conforming 7.5cm x 4.5m
30BDC010	Blue Dot Conforming Bandage 10cm x 4.5m
30BDC010-10	Blue Dot Conforming Bandage 10cm x 4.5m (Pack of 10)
BP 170	Blue Dot Cohesive Bandage 5cm x 4m
171	Blue Dot Cohesive Bandage 6cm x 4m
171-10	Blue Dot Cohesive Bandage 6cm x 4m (Pack 10)
178	Blue Dot Cohesive Bandage 8cm x 4m
178-10	Blue Dot Cohesive Bandage 8cm x 4m
179	Blue Dot Cohesive Bandage 8cm x 4m
179-10	Blue Dot Cohesive Bandage 8cm x 4m
30TDM120	Blue Dot Training Bandage 12cm x 12cm
30TDM120-10	Blue Dot Training Bandage 12cm x 12cm
30BDLC75	Blue Dot Lite Conforming Bandage 7.5cm x 4.5m
BP30BPCR75	Boots Crepe Bandage BP 7.5cm x 4.5m
051067605	Asda Stretch Bandage 5cm x 4m
81414	Medikit Conforming Bandage 5cm x 4.5m
81416	Medikit Conforming Bandage 7.5cm x 4.5m
81416	Medikit Conforming Bandage 10cm x 4.5m
1801007	Astroplast Conforming Bandage 5cm x 4.5m
1801009	Astroplast Conforming badage 7cm x 4m
1801012	Astroplast Conforming Bandage 5cm x 3.6m
1801013	Astroplast Conforming Bandage 7.5cm x 4.5m
1802002	Astroplast Crepe Bandage 5cm x 4m
1802003	Astroplast Crepe Bandage 7.5cm x 4.5m
F18007	St John Ambulance Conforming Bandage 7.5cm x 4.5m
F90241	St John Ambulance Training Dressing Medium (Non-Sterile) 12cm x 12cm
1801009S	Wallace Cameron Conforming Bandage 7.5cm x 4.5m