


UD130		 UNIGLOVES®	
JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745			
QM manual according to DIN EN ISO 13485:2021		Page 1 von 6	
Prepared by: Mr. Dreßler	Approval (content/formal): Mr. Dreßler / Ms. Heuser	Release date: 10.09.2025	Revision: 2
Product Family Examination Gloves			
Document revision:			2

Medical Device	Unigloves Nitrile Gloves PPE Type C
Catalogue number	See annex
Basic UDI-DI according to Part C of Annex VI	4260503143710R3
Intended Purpose	The non-sterile disposable examination gloves are used to protect patients, users or third parties against diseases and provide temporal protection against bacteria, fungi, viruses and certain chemicals. The examination gloves can be used in the laboratory, medical and industrial sector as well as in the domestic area by laypersons and health care users.
Risk Class according to Annex VIII	I

Manufacturer	Unigloves Arzt- & Klinikbedarf Handelsgesellschaft mbH Camp-Spich-Str. 71 53842 Troisdorf-Spich Germany
Single Registration Number according to Article 31	DE-MF-000013340


We hereby declare, on our own responsibility, the conformity of the abovementioned medical device in accordance with Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Unigloves Arzt- & Klinikbedarf Handelsgesellschaft mbH ensures that the medical device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applicable standards and Common Specifications

EN 455-1:2020	
EN455-2:2024	
EN 455-3:2023	
EN 455-4:2009	
Common Specification	None
Conformity assessment	Technical file according to annex II + III of the regulation (EU) 2017/745

Furthermore, we hereby declare that the products as personal protective equipment (PPE) of the category III comply with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 09

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March 2016 and are identical to the PPE that was the subject of the issued EC type examination with the following certificate numbers:

- CE-PI-20230418-01-01-9B

This declaration of conformity is issued under the sole responsibility of the manufacturer.


The PPE is subject to the conformity assessment procedure module C2 under the supervision of the Notified Body 2834.

Applied harmonised standards, national standards or other normative documents	EN ISO 21420:2020, EN ISO 374-1:2016 + A1:2016/ Type C – Test chemical Sodium hydroxide 40%, EN ISO 374-4:2019, EN ISO 374-5:2016
Notified Body	CCQS Certification Services Limited (Kennnummer 2834) Block 1 Blanchardstown Corporate Park, Ballycoolin Road, D15 AKK1 Ireland
Certificates issued	CE-PI-20230418-01-01-9B valid until 26.04.2028
EU Declaration is valid until	26.04.2028


Troisdorf, 29.09.2025




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 Dr. Sandra Heuser
Person responsible
for regulatory compliance

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Article number	Product description	6 / XS	7 / S	8 / M	9 / L	10 / XL	11 / XXL
100*	Unigloves FORMAT® WHITE	1001	1002	1003	1004	1005	NA
101*	Unigloves COBALT PEARL®	1011	1012	1013	1014	1015	NA
350*	Unigloves LIME PEARL®	3501	3502	3503	3504	NA	NA
380*	Unigloves BLACK PEARL®	3801	3802	3803	3804	NA	NA
410*	Unigloves OPAL PEARL®	4101	4102	4103	4104	4105	NA
450*	Unigloves YELLOW PEARL®	4501	4502	4503	4504	4505	NA
460*	Unigloves ORANGE PEARL®	4601	4602	4603	4604	4605	NA
480*	Unigloves VIOLET PEARL®	4801	4802	4803	4804	NA	NA
580*	Unigloves PINK PEARL®	5801	NA	NA	5804	NA	NA
600*	Unigloves FORMAT® BLUE	NA	6002	6003	6004	6005	NA
651*	Unigloves SAPPHIRE PEARL®	6511	NA	6513	NA	NA	NA
680*	Unigloves MINT PEARL®	6801	6802	6803	NA	6805	NA
750*	Unigloves FANCY® ROSE	7501	7502	7503	7504	NA	NA
751*	Unigloves FANCY® GOLD	7511	7512	7513	7514	7515	NA

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752*	Unigloves FANCY® SILVER	7521	7522	7523	7524	7525	NA
753*	Unigloves FANCY® VIOLET	7531	7532	7533	7534	NA	NA
80*0	Unigloves SOFT® NITRIL BLUE	NA	8020	8030	8040	8050	NA
850*	Unigloves MAGENTA PEARL®	8501	NA	NA	NA	8505	NA
880*	Unigloves BLUE PEARL®	NA	NA	NA	NA	8805	NA
980*	Unigloves RED PEARL®	9801	9802	9803	NA	9805	NA
1410*	Unigloves SOFT® NITRIL BLUE 300	NA	14102	14103	14104	14105	NA
700*-200	Unigloves SOFT® WHITE	NA	7002- 200	7003- 200	7004- 200	7005- 200	NA
70*0 W	Unigloves SOFT® NITRIL WHITE PREMIUM	7010 W	NA	NA	NA	NA	NA
800*-200	Unigloves SOFT® BLUE	NA	8002- 200	8003- 200	8004- 200	8005- 200	NA
80*0-374	Unigloves SOFT® NITRIL BLUE PREMIUM	8010- 374	8020- 374	8030- 374	8040- 374	8050- 374	NA
900*-200	Unigloves SOFT® BLACK	NA	9002- 200	9003- 200	9004- 200	9005- 200	NA
GM010*	Unigloves CROSSGUARD	GM0101	GM0102	GM0103	GM0104	GM0105	NA

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GP001*	Unigloves BLUE PEARL®	GP0011	GP0012	GP0013	GP0014	GP0015	NA
GP002+	Unigloves WHITE PEARL®	GP0021	GP0022	GP0023	GP0024	GP0025	NA
GP003*	Unigloves BLACK PEARL®	GP0031	GP0032	GP0033	GP0034	GP0035	NA
GP004*	Unigloves GREEN PEARL®	GP0041	GP0042	GP0043	GP0044	GP0045	NA
GP005*	Unigloves PINK PEARL®	GP0051	GP0052	GP0053	GP0054	GP0055	NA
GP006*	Unigloves RED PEARL®	NA	GP0062	GP0063	GP0064	GP0065	NA
GP007*	Unigloves VIOLET PEARL®	GP0071	GP0072	GP0073	GP0074	GP0075	NA
GP008*	Unigloves SAPPHIRE PEARL®	GP0081	GP0082	GP0083	GP0084	GP0085	NA
GP009*	Unigloves OPAL PEARL®	GP0091	GP0092	GP0093	GP0094	GP0095	NA
GP012*	Unigloves BURGUNDY PEARL®	GP0121	GP0122	GP0123	GP0124	GP0125	NA
GP101*	Unigloves COBALT PEARL®	GP1011	GP1012	GP1013	GP1014	GP1015	NA
GP350*	Unigloves LIME PEARL®	GP3501	GP3502	GP3503	GP3504	GP3505	NA
GP680*	Unigloves MINT PEARL®	GP6801	GP6802	GP6803	GP6804	GP6805	NA
GP850*	Unigloves MAGENTA PEARL®	GP8501	GP8502	GP8503	GP8504	GP8505	NA
GS004*	Unigloves UNICARE Blue Nitrile	NA	GS0042	GS0043	GS0044	GS0045	NA
GS025*	Unigloves UNICARE Black Nitrile	GS0251	GS0252	GS0253	GS0254	GS0255	NA

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GS003*	Unigloves UNICARE Nitrile	GS0031	GS0032	GS0033	GS0034	GS0035	NA
GS700*	Unigloves UNICARE White Nitrile	NA	GS0072	GS0073	GS0074	GS0075	NA
GS900*	Unigloves UNICARE Black Nitrile	NA	GS9002	GS9003	GS9004	GS9005	NA



EC Declaration of Conformity

TF-04

Sterile Saline Topical Irrigation Solution

Version: 7.00

Page 1 of 1

This declaration of conformity is issued under the sole responsibility of the manufacturer

Crest Medical Ltd
Unit 5, Farrell Industrial Estate
Howley Lane, Warrington,
WA1 2PB
United Kingdom

Previously of:
3 Chesford Grange, Woolston,
Warrington, WA1 4RQ

Crest Medical Ltd declares that the following medical device range

7912	Eye care solutions irrigation solution sterile
4002	Irripod Topical Irrigation Solution Sterile
2404061	20ml Astroplast sterile saline pods (Case 36 x box 25)
2404084	20ml Astroplast sterile saline pods (Box 25) (96891-0001)
2405006	20ml Astroplast sterile saline pods (Box 25)
2405012	20ml Astroplast clipped twist n pull saline eye wash pods (Box 25)
2405095	20ml Astroplast Twist N Pull Sterile Saline Pods (Case 30 x Box 25) (13348) (543391)
2404096	5ml Astroplast ultra saline eye wash pods (case 50) (10206) (569388)
2405099	20ml Astroplast Sterile Saline Pods (Box 25) INNOVATIVE SAFETY SUPPLY
2405013	5ml Astroplast ultra saline eye wash pods (Box 10)
5362	Alvita sterile saline pods

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No.2936 (2008) that transposes the Directive into UK National Law and the UK MDR 2002 as amended.

is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex V section 3 of Directive 93/42/EEC under the supervision of SGS House Noorderlaan 87 2030 Antwerp Belgium, Notified Body Number 1639, CE certificate number GB19/964731.


Classification: 2a Sterile- Rationale Annex IX (93/42/EEC) – Rule 5 – “All invasive devices with respect to body orifices, other than surgically invasive devices, intended for short term use”.

(Part II para 7(1), UK MDR 2002 as amended)

And

Annex IX (93/42/EEC) – Rule 4 “All non-invasive devices which come into contact with injured skin are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound

Mathew Courtney, Director 14 August 2025

	UK Declaration of Conformity	TF-06
	Sterile Wound Cleansing Wipes & Plastic Free Wound Cleansing Wipes	
	Version: 8.00	Page 1 of 2

United Kingdom Medical Devices Regulations 2002

This Declaration of Conformity is issued under the sole responsibility of the manufacturer to state that the requirements specified in the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) have been fulfilled in relation to the devices in this declaration.

Name and address of Manufacturer:	Crest Medical Limited. Unit 5, Farrell Industrial Estate, Howley Lane, Warrington, WA1 2PB, UK		
Product Name:	Sterile Wound Wipes		
Product Codes or Catalogue Numbers:	As per Annex 1		
Intended Purpose:	The sterile wound cleansing wipes and product family are intended for topical cleansing and wound management.		
GMDN Code:	58475	MHRA Reg. No.:	5922
Risk Class:	Class IIa	Classification Rules:	Rule 4
Sterile:	Yes	Measuring Function:	No
Approved Body:	SGS United Kingdom Ltd, Rossmore Business Park, Ellesmere Port, Cheshire CH65 3EN, UKCA 0120		
Conformity Assessment Procedure:	Annex V – Production Quality Assurance		
Certificate Type(s) and Reference Number(s):	UKCA Certificate: GB22/00000372 ISO 13485 Certificate: GB98/12980		

Declaration Signature:


Date: 1 September 2025

Location: As above

Name: Matthew Courtney

Position: Director

Signed:  _____

	UK Declaration of Conformity	TF-06
	Sterile Wound Cleansing Wipes & Plastic Free Wound Cleansing Wipes	
	Version: 8.00	Page 2 of 2

ANNEX 1 – Device Listing

Product Code / Catalogue No.	Device Description/Name
86972	Blue Dot Once Sterile Wound Cleansing Wipes (Box 100)
86974	Blue Dot Once Sterile Wound Cleansing Wipes (Bag 10)
86975	Blue Dot Once Sterile Wound Cleansing Wipes - Single
86975P	Blue Dot Once Wound Cleansing Wipes – Plastic Free
86976	Blue Dot Once Sterile Wound Cleansing Wipes (Case 2,000)
1601002	Astroplast Sterile Wound Cleansing Wipes (Box 100)
1601026	Astroplast Sterile Wound Cleansing Wipes (Pack 10)
RO4223B	Astroplast Sterile Wound Cleansing Wipes
F11508	St John Ambulance Sterile Cleansing Wipe - Single
F18018	St John Ambulance Sterile Cleansing Wipes (Pack of 10)
1601026S	Wallace Cameron Sterile Wound Cleansing Wipes (Pack 10)
RO4223BS	Wallace Cameron Sterile Wound Cleansing Wipes



EC Declaration of Conformity

TF-13

Advacare/Astroplast Low/Non- Adhesive Wound Dressing Sterile

Version: 5.00

Page 1 of 1

This declaration of conformity is issued under the sole responsibility of the manufacturer

Crest Medical Ltd
Unit 5, Farrell Industrial Estate
Howley Lane
Warrington
WA1 2PB
United Kingdom

Previously of:
3 Chesford Grange, Woolston,
Warrington, WA1 4RQ

Crest Medical Ltd declares that the following medical device range,

Product	Description Code
86957	Advacare Low-Adherent Wound Dressing Sterile 5cm x 5cm (single)
86958	Advacare Low-Adherent Wound Dressing Sterile 5cm x 5cm (Box 100)
86959	Advacare Low Adherent Wound Dressing Sterile 7.5cm x 7.5cm (Single)
86960	Advacare Low-Adherent Wound Dressing Sterile 7.5cm x 7.5cm (Box 100)
86961	Advacare Low Adherent Wound Dressing Sterile 10cm x 10cm (Single)
86962	Advacare Low-Adherent Wound Dressing Sterile 10cm x 10cm (Box 100)
1403035	Astroplast Non-Adherent Wound Dressing 5cm x 5cm (Single)
1403036	Astroplast Non-Adherent Wound Dressing 10cm x 10cm (Single)
1403037	Astroplast Non-Adherent Wound Dressing 7.5cm x 7.5cm (Single)

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No.2936 (2008) that transposes the Directive into UK National Law

Is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex V section 3 of Directive 93/42/EEC under the supervision of SGS House Noorderlaan 87 2030 Antwerp Belgium, Notified Body Number 1639, CE certificate number GB22/00000372.

Classification: I Sterile- Rationale Annex IX (93/42/EEC) – Rule 4 – “All non-invasive devices which come into contact with injured skin and are intended to be used as a mechanical barrier, for compression or for absorption of exudates.”.

Matthew Courtney, Director.

1 September 2025



This declaration of conformity is issued under the sole responsibility of the manufacturer

Crest Medical Limited,
Unit 5
Farrell Industrial Estate
Howley Lane
Warrington
WA1 2PB
United Kingdom

Crest Medical Ltd declares that the following medical device range,

Product code	Description
85430	Blue Dot Sterile Gauze Swabs 8 Ply 5cm x 5cm (Pack 5)
85431	Blue Dot Sterile Gauze Swabs 8 Ply 7.5cm x 7.5cm (Pack 5)
85432	Blue Dot Sterile Gauze Swabs 8 Ply 10cm x 10cm (Pack 5)
85433	Blue Dot Sterile Gauze Swabs 8 Ply 5cm x 5cm Box of 20 (Pack 5)
85435	Blue Dot Sterile Gauze Swabs 8 Ply 7.5cm x 7.55cm Box of 20 (Pack 5)
85436	Blue Dot Sterile Gauze Swabs 8 Ply 10cm x 10cm (Box of 20)
85440	Blue Dot Sterile Gauze Swabs 12 Ply 7.5cm x 7.5cm
13888	Alvita 5 Sterile Gauze Swabs 7.5cm x 7.5cm 8 ply (36 Pack of 5)
ALV353/2)3656451	
49-37-732	Boots Sterile Absorbent Gauze BP 90cm x 3m 8ply
49-37-406	Boots Sterile Gauze Swabs 7.5cm x 7.5cm (Pack of 5)

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No.2936 (2008) that transposes the Directive into UK National Law


is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex V section 3 of Directive 93/42/EEC under the supervision of SGS House Noorderlaan 87 2030 Antwerp Belgium, Notified Body Number 1639, CE certificate number GB19/964731.

Classification: I Sterile- Rationale Annex IX (93/42/EEC) – Rule 4 – “All non-invasive devices which come into contact with injured skin and are intended to be used as a mechanical barrier, for compression or for absorption of exudates.”.

Matthew Courtney, Director 4th September 2025




	EU Declaration of Conformity	TF-022
	Non-Sterile Bandages	
	Version: 3.02	Page 1 of 4

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:	5039139TF015Q7		
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		

	EU Declaration of Conformity	TF-022
	Non-Sterile Bandages	
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Declaration Signature:


Date: 8 May 2026

Location: As above

Name: Matthew Courtney

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

Signed:  _____

	EU Declaration of Conformity	TF-022
	Non-Sterile Bandages	
	Version: 3.02	Page 3 of 4

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

	EU Declaration of Conformity	TF-022
	Non-Sterile Bandages	
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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

	EU Declaration of Conformity	TF-25
	Adhesive Tapes	
	Version: 2.03	Page 1 of 5

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:	5039139TF016Q9		
Product Name:	Adhesive Tapes		
Product Codes or Catalogue Numbers:	As per Annex 4 – Device Listing		
Intended Purpose:	Adhesive tapes are suitable for general surgical trip wound or other medical sticking and fixation, such as fixed conduit and catheter, plaster fixation and reinforcement.		
GMDN Code:	16866 (non-silicone) 58749 (silicone)	EMDN Code:	M9099
Risk Class:	Class I	Classification Rules:	MDR 2017/745 ANNEX VIII 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		

	EU Declaration of Conformity	TF-25
	Adhesive Tapes	
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Declaration Signature:


Date: 13 May 2026

Location: As above

Name: Matthew Courtney

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

Signed:  _____

	EU Declaration of Conformity	TF-25
	Adhesive Tapes	
	Version: 2.03	Page 3 of 5

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


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ISO 13485	Medical Devices – Quality Management Systems –Requirements for regulatory purposes.
EN ISO 14971	Medical devices. Application of risk management to medical devices
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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 – Tests for In Vitro Cytotoxicity
EN ISO 10993-12	Biological Evaluation of Medical Device-: Test for irritation
EN ISO 10993-10	Biological Evaluation of Medical Device-: Test for Skin sensitization

ANNEX 4 – Device Listing

Product Code / Catalogue No.	Device Description/Name
30BMT025	Microporous Tape 2.5cm x 5m Boxed (Each)
30BMT125	Microporous Tape 1.25cm x 5m Boxed (Each)
30BMT050	Microporous Tape 5.0cm x 5m Bagged (Each)
12803	Microporous Tape 1.25cm x 10m - (Each)
12822	Microporous Tape 2.5cm x 10m – Box of 12
12832	Microporous Tape 5.0cm x 10m – Box of 6
12840	Microporous Tape 7.5cm x 10m – Box of 6
12823	Microporous Tape 2.5cm x 10m (Each)
12808	Microporous Tape 1.25cm x 10m (Box 24)
12824	Microporous Tape 7.5cm x 10m (Box 6)

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2005001	Microporous Tape 1.25cm x 5m
2005015	Microporous Tape 2.5cm x 5m
2005016	Microporous Tape 5cm x 5m
2005017	Microporous Tape 2.5cm x 5m (Case 48)
2005020	Microporous Tape 2.5cm x 5m (case 36)
BP12823	Microporous Tape Boots 2.5cm x 5m
204441S	Zinc Oxide Tape 1.25cm x 10m (Each)
204441	Zinc Oxide Tape 1.25cm x 10m (Pack of 48)
204442S	Zinc Oxide Tape 2.5cm x 10m (Each)
204442	Zinc Oxide Tape 2.5cm x 10m (Pack of 24)
204443S	Zinc Oxide Tape 5.0cm x 10m – (Each)
204443	Zinc Oxide Tape 5.0cm x 10m – (Pack of 12)
204444S	Zinc Oxide Tape 7.5cm x 10m – (Each)
8000011	Zinc Oxide Tape 2.5cm x 10m – (Box of 36)
598101	Zinc Oxide Tape 2.5cm 5m- (Each)
8000007	Silk Surgical Tape 1.25cm x 10m – (Box of 24)
8000008	Silk Surgical Tape 2.5cm x 10m – (Box of 12)
8000013	Silk Surgical Tape 5cm x 10m
8000009	Dressing Retention Sheet Soft Cloth Surgical Tape 5.0cm x 10m Boxed (Each)
8000010	Dressing Retention Sheet Soft Cloth Surgical 10cm x 10m Boxed (Each)
8000014NHS	Dressing Retention Sheet Soft Cloth Surgical 15cm x 10m Boxed (Each)
8000015NHS	Dressing Retention Sheet Soft Cloth Surgical 2.5cm x 10m (Each)
8000016NHS	Dressing Retention Sheet Soft Cloth Surgical 20cm x 10m (Each)
8000000	Polyethylene Transparent Surgical Tape 1.25cm x 5m – Boxed (Each)
8000001	Polyethylene Transparent Surgical Tape 2.5cm x 5m – (Box of 12)
8000001S	Polyethylene Transparent Surgical Tape 2.5cm x 5m – (Single)
8000002	Polyethylene Transparent Surgical Tape 2.5cm x 5m - Each
8000003	Polyethylene Transparent Surgical Tape 5.0cm x 5m – Boxed (Each)
8000004	Polyethylene Transparent Surgical Tape 7.5cm x 5m – Boxed (Each)
8000005	Plastic Perforated Medical Tape 1.25cm x 10m – (Box of 24)
8000006	Plastic Perforated Medical Tape 2.5cm x 10m – (Box of 12)
8000012NHS	Plastic Perforated Medical Tape 5cm x 10m – (Box 6)
85502	Elastic Adhesive Tape 2.5cm x 4.5m (Each)
85503	Elastic Adhesive Tape 2.5cm x 4.5m – (Box of 12)
30WSBP30	Waterproof Tape 2.5cm x 5m (Each)
2002003	Waterproof Tape 2.5cm x 5m (Each)
2002016	Waterproof Tape 2.5cm x 5m (Case 36)
30BTCS25	Blue Detectable Tape 2.5cm x 5m – (Each)
30BTCS25C	Blue Detectable Tape 2.5cm x 5m – (Pack of 12)
2003001	Blue Detectable Tape 2.5cm x 5m
2003004	Blue Detectable Tape 2.5cm x 5m (Case 36)
90914	PE Tape 2.5cm x 10m
12802	Medical Tape 1.25cm x 10m
12824	Medical Tape 7.5cm x 10m

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2001011	Fabric Tape 2.5cm x 5m
2001012	Fabric Tape 5cm x 5m
80115	Microporous Tape 2.5cm x 5m
F18011	St John Ambulance Microporous Tape 2.5cm x 10m
2005015S	Wallace Cameron Sustainable Microporous Tape 2.5cm x 5m (Each)
98-77-789	Boots Multi-Purpose Silicone Tape 2.5cm x 3m (Each)