30 FMD 120 ) We do not have MSDS For these products. 30 FBOT 16 ) 30 BCRE 16

## **CREST MEDICAL LIMITED**

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: STERILE FIRST AID DRESSINGS					
APPROVED:	PPROVED:		AUTHORISED:		
DATE:		DATE:			
ISSUE:	7	8	9	1000110	
DATE:	16/03/10	08/04/14	23/09/15		

## **APPENDIX II**

## **EC DECLARATION OF CONFORMITY**

Crest Medical Limited 3, Chesford Grange, Woolston, Warrington, Cheshire. WA1 4RQ

declares that the medical device range described in Appendix V

#### STERILE FIRST AID DRESSINGS

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 Directives into UK National Law,

is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII plus Annex V (sterility aspects) of Directive 93/42/EEC under the supervision of Intertek AMTAC Certification services, Notified Body Number 0473.

Classification: Class 1 Sterile – Rationale Annex IX (93/42/EEC) – Rule 4 "All non-invasive devices which come into contact with injured skin are in class 1 if they are intended to be used as a mechanical barrier or absorption of exudates.

Warrington 23/09/15

Alastair Maxwel Managing Director

## **CREST MEDICAL LIMITED**

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: BLUE DOT TRIANGULAR BANDAGES				R BANDAGES	
APPROVED:	APPROVED:		AUTHORISED:		
DATE:		DATE:			
ISSUE:	4	5	6		
DATE:	16/03/10	13/03/14	15/06/15		

## **APPENDIX II**

## **EC DECLARATION OF CONFORMITY**

Crest Medical Limited 3, Chesford Grange, Woolston, Warrington, Cheshire. WA1 4RQ

declares that the medical device range described in Appendix V

### **BLUE DOT TRIANGULAR BANDAGE**

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 VII of Directive 93/42/EEC

Classification: Class 1: Non-Sterile – Rationale Annex IX (93/42/EEC) – Rule 1 "All non invasive devices

are in class I unless one of the rules set out hereafter applies". No other rules apply.

Warrington 15/06/15

Alastair Maxwell Managing Director

# 30 BMTO2S - We do not have MSOS for this product. 20 4442S + 204443

Medical Suppliers to the medical industry

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPILTXT		
PRODUCT RANGE			: ADHESIVE TAI	PES	•
DATE: 892015		DATE: 89 2015			
ISSUE:	2	3	4	5	
DATE:	24/09/07	16/03/10	20/03/14	08/09/15	

## **APPENDIX II**

## EC DECLARATION OF CONFORMITY

Crest Medical Limited 3, Chesford Grange, Woolston, Warrington, Cheshire. WA1 4RQ

declares that the medical device range described in Appendix V

### **ADHESIVE TAPES**

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 VII of Directive 93/42/EEC.

Classification: Class 1 Non-Sterile - Rationale Annex IX, (93/42/EEC) - Rule 1 "All non-invasive devices which do not come into contact with injured skin are in class I unless one of the rules set out

hereafter applies". No other rules apply.

Warrington 08/0915

Alastair Maxwell Managing Director

Page 1 of 1





30 BDC075 - We do not have MSDS for this product. 30 BDCR10

## CREST MEDICAL LTD.

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: CREST MEDICAL NON STERILE BANDAGES					
APPROVED:		AUTHORISED:			
DATE:		DATE:			
ISSUE:	6	7	8		
DATE:	30/04/13	14/04/14	1/10/15		

## <u>APPENDIX II</u>

## **EC DECLARATION OF CONFORMITY**

Crest Medical Limited 3, Chesford Grange, Woolston, Warrington, Cheshire. WA1 4RQ United Kingdom

declares that the medical device range described in Appendix V

## NON STERILE BANDAGES

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 the UK National Law,

is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII of Directive 93/42/EEC.

Classification: Class 1: Non-Sterile – Rational Annex IX (93/42/EEC)- Rule 1 - Non-invasive device.

Warrington 1/10/15

Alastair Maxwell Managing Director

# 30 PEWP10 Blue Dot Associted Wash Proof Plastors We do not have MSDS for this product

# CREST MEDICAL LIMITED.

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPILTXT		
PRODUCT RANGE: STERILE ADHESIVE PLASTERS				3	
APPROVED JOSON  DATE: 2LL 8 2015		DATE: 211 82015			
ISSUE:	1	2	3		
DATE:	29/03/11	21/05/13	24/08/15		

## APPENDIX II

## EC DECLARATION OF CONFORMITY

Crest Medical Limited 3, Chesford Grange, Woolston, Warrington, Cheshire. WA1 4RQ

declares that the medical device range described in Appendix V

## **BLUE DOT STERILE ADHESIVE PLASTERS**

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 national standard BS EN ISO 13485 transposing the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII plus Annex V (sterility aspects) of Directive 93/42/EEC

Warrington 24/08/15

Alastair Maxwell Managing Director

## **Technical Data Sheet For 30REVA01**

ltem	Technical Requirement		
Material of film	ethylene-vinyl acetate copolymer		
Thickness of film	0.11mm(±10%)		
Size of film	20*20cm(±1cm)		
Material of filter	polypropylene		
Size for inlet port of filter	1.5cm(±0.2cm)		
Diameter of outlet for filter	3.6cm*1.55cm		
Appearance	Appearance should be complete, uniform color, should be neat and clean, no foreign objects		



# MATERIAL SAFETY DATA SHEET Sterile Eye Wash

Reviewed 29/12/2012

## 1. Identification of the Substance/Preparation and the Company

Trade Name: Sterile Eye Wash

Product Code: 2143 500ml Blue Dot Sterile Eye Wash Solution

2144 250ml Blue Dot Sterile Eye Wash Solution

EYE500C 500ml Blue Dot Sterile Eye Wash Solution With Cap

Use of the preparation: A liquid for irrigation and cleansing of the eyes

Company: Crest Medical Ltd

Healthcare Enterprise House

17 Chesford Grange

Woolston Warrington, WA1 4RQ, UK

Contact: Tel: +44 (0) 845 230 2092

Fax: +44 (0) 845 230 2091 Email: sales@crestmedical.co.uk www.crestmedical.co.uk

## 2. Hazard Identification

This preparation is, according to the conventional method of Directive 1999/45/EC and subsequent amendments, classified as not "Hazardous".

## 3. Composition/information on ingredients

CAS No: Not applicable, preparation is a mixture. EINECS No: Not applicable, preparation is a mixture.

Composition: An aqueous solution containing 0.9% w/v sodium chloride EP.

## 4. First Aid Measures

Based on the composition of this preparation none would be required.

## 5. Fire Fighting Measures



Only the packaging containing the preparation would burn.

Suitable extinguishing media: Water spray/fog, foam, carbon dioxide and dry powder.

Standard protective equipment should be worn by fire-fighters.

In the event of a large fire toxic fumes containing oxides of carbon may be formed, which would necessitate the use of a self-contained breathing apparatus.

## 6. Accidental Release Measures

Personal precautions: None required.

Methods for cleaning-up: Mechanically collect any packaging for subsequent disposal and then rinse any spilled preparation to a drain with water.

## 7. Handling and Storage

Handling: No special measures required.

Storage: Store under normal warehouse conditions.

## 8. Exposure Controls/Personal Protection

Exposure controls: No assigned values for the ingredients of this preparation.

Personal protection: None required.

## 9. Physical and Chemical Properties

Appearance: Preparation is a clear colourless liquid

Odour: Preparation is odourless pH of preparation: 4.5 – 7.0

Boiling point of preparation: ca 100°C

Flash point of preparation: N/A

Flammability: Preparation is non flammable

Solubility: Preparation is completely miscible with water

## 10. Stability and Reactivity

This preparation is stable under normal conditions of storage/use and no chemical incompatibility is known.

## 11. Toxicological Information



Based on the ingredients present and their concentrations this preparation is, according to the conventional method of Directive 1999/45 EC and subsequent amendments, classified as not "Dangerous" according to health criteria.

## 12. Ecological Information

Based on the ingredients present and their concentrations this preparation is, according to the conventional method of Directive 1999/45 EC and subsequent amendments, classified as not "Dangerous" to the environment.

## 13. Disposal Considerations

Dispose of the packaging according to local and national regulations whilst the preparation can be discharged to any drain.

## 14. Transport Information

This preparation is classified as not "Hazardous" for transport purposes

ADR - Not regulated

IMDG - Not regulated

IATA – Not regulated

## 15. Regulatory Information

This preparation is not classified as not "Hazardous" for labeling purposes.

Label for supply:

**Active Ingredient** 

0.9% w/v sodium chloride EP

Directions for Use:

To open: Twist cap smoothly to break seal and remove cap.

How to use: Position container above the eye and gently squeeze so that the fluid flows freely across the eyeball to the outer corner.

Dose: Irrigate and cleanse the eye(s) with as much solution as required.



## 16. Other Information

This Safety Data Sheet, which takes into consideration the requirements of Directive 1999/45/EC plus subsequent amendments, has been prepared in accordance with Regulation (EC) No 1272/2008 as amended by Regulation (EC) No 453/2010. It is believed to be correct and corresponds to the latest state of scientific/technical knowledge but all data, instructions, recommendations and/or suggestions are made without guarantee.