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Änderungsnummer / Change Master: DX_SRA_13


Objektverknüpfungen / Object Links:

JBX 40010507 000 02 BPF Tensospray
 JBX 40010507 000 04 BPF Tensospray

Dokumentenstückliste / Document Structure:

JBN ISO 9001 000 Qualitätsmanagementsysteme - Anforderung
 JBN ISO 13485 000 Medical devices - Quality management sys
 JBN ISO 13485 TECH CORR 1 000 Medical devices - Quality management sys
 JBN DIN EN ISO 9001 000 Qualitätsmanagementsysteme - Anforderung
 JBN DIN EN ISO 9001 BER. 000 Quality managemant systems - Requirement
 JBN DIN EN ISO 13485 000 Medizinprodukte - Qualitätsmanagementsys


Status	Responsible	Date
IE in Erstellung	WITTEC	21.05.2014
AF Freigabeanford.	BEHRENTA	22.05.2014
FR freigegeben	WITTEC	23.05.2014

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Product Safety Data Sheet

Document will not be automatically updated


1.0 Name of the product	Tensospray®
2.0 Product description	
2.1 Description	The product is used for helping the adherence of bandages to patients. It provides a protective layer to the skin before the application of a pre-wrap tape to elastic adhesive bandages.
2.2 Characteristics	<ul style="list-style-type: none"> - Provides a non-slip layer for the application of tapes and elastic adhesive bandages. - Reduces skin trauma on removal of tapes and elastic adhesive bandages. - Removable with soap and water. - Easy to apply - Colourless- will not stain hands or clothes
2.3 Intended use	Adhesive spray for fixation of bandages.
2.4 Instructions for use	Printed on the product
2.5 CE-class GMDN - code	CE Class I, Rule 12 GMDN Code: 10035
2.6 Duration of application / Period of use	Depending on the medical device which is fixed with Tensospray®.
2.7 Composition	Material components: Butane, Methylal, Denatured alcohol, Isobutane, Propane Glyceryl Rosinate, Paraffinum Perliquidum
2.8 Latex in product and packaging material	Product composition: No latex content Packaging material: No latex content
2.9 Phthalate in product and packaging material	No content of DEHP (Di(2-ethylhexyl)phthalate) in product. No content of DEHP (Di(2-ethylhexyl)phthalate) in packaging.
2.10 Controls	Visual Characteristics, Functionality

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2.11 Product range		
Reference	Size	Cans per shipping case
71602-00	300 ml	12
2.12 Storage conditions	Requirements for storage rooms and vessels pay attention to TRG 300. Avoid heating and direct sunlight. Keep container tightly closed; open and handle with care. Always keep in containers of same material as the original one.	
2.13 Shelf life/Storage time	2 years.	
2.14 Sterilization	Product is not sterile.	

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3.0 Safety information of Tensospray®	
3.1 Warnings and precautions for use	For external use only. Extremely flammable aerosol. Pressurized container: May burst if heated. If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read label before use. Keep away from heat / sparks / open flames / hot surfaces. – No smoking. Do not spray on an open flame or other ignition source. Pressurized container: Do not pierce or burn even after use. Avoid breathing spray. Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F. Do not use the product in another way of what it is intended to. Use and store only in a well-ventilated area. Do not spray for a long time. Do not spray in the area of eyes and broken and sore skin.
3.2 Flammable or combustible properties	Extremely flammable, transparent liquid
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contra Indications	No known contra indications.
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used
3.6 Transport Precautions	Requirements for storage rooms and vessels pay attention to TRG 300. Avoid heating and direct sunlight.
3.8 First Aid	a) Inhalation: Fresh air. Get medical attention if pain still persists. b) Contact with skin: Wash off with soap and water. Do NOT use solvents or thinners! c) Contact with eyes: Separate eyelids, wash the eyes thoroughly with water (15 min.). If signs/symptoms persist, get medical attention. d) Ingestion: Rinse mouth thoroughly with water. If swallowed, immediately consult a doctor, showing him the label.
3.9 Disposal	Controlled incineration / landfill according to local environmental health guidelines.

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4.0 General information	
4.1 Name, address and telephone number of legal manufacturer	BSN medical GmbH Quickbornstraße 24 D-20253 Hamburg GERMANY Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
4.2 Certificates for Quality Management	ISO 9001 /DIN EN ISO 9001; ISO 13485 / DIN EN ISO 13485 (notified body: Dekra)

History

Version/Date	Page /Item	Description of Change
01 / 09.07.2011	Set up new document	
02 / 09.05.2014	Whole document Page 2 / item 2.2 Page 2 / item 2.5 Page 4 / item 3.1 Page 4 / item 3.8	Adaption to new design Adaption of characteristics Change of CE class IIa, rule 9 to CE class I, rule 12 Update of warnings and precautions for use Update of first aid measures