Änderungsnummer / Change Master: C1187

Objektverknüpfungen / Object Links:

JBX 40007433 000 05 BPF Coverplast Detectable (steril)
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Dokumentenstückliste / Document Structure:

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
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 11135 000 Sterilisation von Produkten für die Gesu
JBN DIN EN 556-1 000 Sterilisation von Medizinprodukten -Anfo
JBN DIN EN 556-1-BER-1 000 Sterilization of medical devices - Requi
JBN ISO 11135 000 Sterilization of health-care products -

Status		Responsible	Date
IE	in Erstellung	AEVERMANNM	26.02.2015
AF	Freigabeanford.	AEVERMANNM	04.03.2015
FR	freigegeben	OTTEJ	05.03.2015

Product Data Sheet

This document is thought as a data base which gives all information for promotion material, tender business applications and other marketing related activities.

EUROPEAN AND US REGULATIONS

The EU Chemical Agents Directive (98/24/EC) is the legislation designed to control the risk to users arising from exposure to harmful substances. The European Directive 1999/45/EC defines hazardous preparation and states the requirements for classification, packaging and labelling of dangerous preparations. The information within this Directive indicates that this medical device does not require a safety data sheet. Therefore, a Material Safety Data Sheet according to the Directive 91/155/EEC is not necessary for the product mentioned in this document.

The occupational Safety and Health (OSHA) regulation 29 CFR is the standard in the USA which ensures the hazards of chemicals are evaluated and that information regarding safety is communicated to employers and employees. Under the terms of this regulation (29CFR.1910.1200 b, c) this medical device is classed as an article based on the definition: " A substance which under normal conditions of use does not release more than very small quantities, e.g. minute or trace amounts of a hazardous chemical and does not pose a physical hazard or health risk to employees." Articles and Medical Devices do not require a Material Safety Data Sheet to comply with the requirements of Regulation 29CFR.

All relevant safety aspects are taken into consideration within the conformity process for CE-marking according to the Medical Device Directive 93/42/EEC. To fulfil these requirements, BSN medical runs a quality management system according to EN ISO 9001 und EN ISO 13485 and performs risk management according to EN ISO 14971 for all products.

The device when used as intended contains no substances which pose a risk to the health of the patient or user. The composition of the medical device is enclosed below so that you may review for your own risk assessment.

1.0 Name of the product	**Coverplast® Detectable**
2.0 Product description	
2.1 Description	Coverplast Detectable First Aid Dressings consists of a blue film, coated evenly with an acrylic adhesive. The nonwoven is laminated onto an aluminium foil that is coated with a synthetic rubber based hotmelt mixed with tungsten powder. The absorbent pad is centrally located on the adhesive surface of the blue substrate. The dressings are individually sealed in printed paper and EO-sterilised.
2.2 Characteristics	- Metal detectable / electromagnetically detectable: contains aluminium foil for non-ferrous detection - X – ray detectable: Tungsten filaments - Highly absorbent, low adherent pad - Breathable / helps to prevent skin maceration - Film provides two way protection against viral and bacterial contamination, reduces risk of secondary wound infection - Waterproof - Impermeable to oil and fat - Film acts as bacterial barrier - Conformable - Skin friendly acrylic adhesive - Visually detectable: Signal Blue contrast colour - Sterile
2.3 Intended use	For minor wounds like cuts, lacerations, abrasions, after blood withdrawal or vaccination in situations where dressings need to be detectable if lost, especially in the food industry.
2.4 Instructions for use	Instructions for use not necessary for class 1 products.
2.5 CE-class **GMDN - code**	Class 1s Rule 4 GMDN Code: 44990

2.6 Composition	Components of the product: Substrate Blue coloured film made of polyurethane and polystyrene. Weight: 75 ± 10 g/m² Adhesive mass Transparent acrylic adhesive mass Quantity: 33 + 5 / - 3 g/m² Wound pad White, non woven pad made of viscose and PE. The wound side is covered with a net of micro perforated film made of polyethylene Weight of uncoated pad laminated with aluminium foil: 200 g/m² ± 20 g/ m² The nonwoven is laminated onto an aluminium foil that is coated with a synthetic rubber based hotmelt mixed with tungsten powder.
2.7 Latex in product and packaging material	Product composition: No latex content Packaging material: No latex content
2.8 Duration of application / Period of use	Apply a plaster repeatedly until the skin has healed completely.
2.9 Phthalate in product and packaging	No content of phthalate in product No content of phthalate in packaging
2.10 Controls	Finished product: Adhesive strength Permeability to water vapour Pull off behaviour covering

2.11 Product range

Assortment	Size	Pieces per box	Per shipper	Product code
Coverplast® Detectable	160 mm x 20 mm	50 plasters	24	71176-01
Coverplast® Detectable	25 mm x 72 mm	50 plasters	6	71176-02
Coverplast® Detectable	Assortment	40 plasters	6	71176-03
Coverplast® Detectable	72 mm x 22 mm	100 plasters	36	72143-09
Coverplast® Detectable	38 mm x 38 mm	100 plasters	48	72143-10
Coverplast® Detectable	72 mm x 50 mm	100 plasters	36	72143-11
Coverplast® Detectable	50 mm x 44 mm	50 plasters	60	72143-13
Coverplast® Detectable	Assortment	95 plasters	24	72143-18

Coverplast® Detectable	12 x 72 mm x 22 mm 8 x 38 mm x 38 mm	20 plasters	72	72143-19
Coverplast® Detectable	72 mm x 22 mm	1200 plasters	1	72180-00
2.12 Storage conditions	Dry, clean and without exposure to direct sunlight			
2.13 Shelf life/Storage time	5 years			
2.14 Sterilization	Product is sterilized by EO sterilization acc. to DIN EN 556-1 and DIN EN ISO 11135 / ISO 11135.			

3.0 Safety information of Coverplast® Detectable	
3.1 Warnings and precautions for use	Do not use on patients with known intolerance to acrylic adhesives.
3.2 Flammable and combustible properties	Combustible solid.
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contraindications	Known intolerance to acrylic adhesives.
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used.
3.6 Transport Precautions	Not applicable.
3.7 First Aid	a) Inhalation: Not applicable b) Contact with skin: Not applicable c) Contact with eyes: Not applicable d) Ingestion: Not applicable
3.8 Disposal	Controlled incineration/ landfill according to local environmental health guidelines.

4.0 General information	
4.1 Name, address and telephone number of legal manufacturer	BSN medical GmbH Quickbornstrasse 24 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 / 13.06.2007	Set up new document	
02 / 30.07.2008	1 and 2	- New Composition of wound pad (without iron) - Revision of claims
03 / 19.03.2012	All pages	- Change from PD to PSDS - General update
04/ 04.03.2015	Page 3 / item 2.2 Page 4 / item 2.11 Page 5 / item 2.12 Page 5 / item 2.13 Page 5 / item 2.14 Page 6 / item 3.7 Page 6 / item 3.10 Page 7 / item 4.2	Viral barrier deleted, no evidence 2 Narts added (-02 and -03) Adjustment of storage conditions shelf life changed from 3 to 5 years Sterilization added Handling/ Use/ Protecting Clothing deleted Additional information deleted international standards added