**Änderungsnummer / Change Master: 3.22.010**

**Objektverknüpfungen / Object Links:**

JBX 40012612 000 01 BPF Cutisoft Cotton Viskers NST, Typ 17

**Dokumentenstückliste / Document Structure:**

JBN DIN EN ISO 9001 000 Qualitätsmanagementsysteme - Anforderung
JBN DIN EN ISO 13485 000 Medizinprodukte - Qualitätsmanagementsys
JBN DIN EN ISO 14971 000 Medizinprodukte - Anwendung des Risikoma
JBN ISO 14971 000 Medical devices - Application of risk ma

| Status | | Responsible | Date |
|---|---|---|---|
| IE | in Erstellung | KRUEGAN | 20.10.2010 |
| AP | Prüfanforderung | PALLUCHB | 21.12.2010 |
| AF | Freigabeanford. | ARNETHA | 21.12.2010 |
| FR | freigegeben | SCHWANKED | 04.01.2011 |

# Product Safety Data Sheet

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**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** | **Cutisoft® Cotton Viskers, non sterile, Typ 17** |
| **2.0 Product description** | |
| **2.1 Description** | Cutisoft® Cotton Viskers non sterile, Typ 17 are non sterile plain woven gauze swabs/compresses made of cotton. |
| **2.2 Characteristics** | - Swabs<br>- 100% cotton<br>- Made from high quality gauze<br>- Oxygen bleached<br>- White colour<br>- 17-thread<br>- Suitable for inclusion in procedure an supplementary packs<br>- Can be sterilized<br>- Absorbent<br>- Absorption of exudates<br>- Skin friendly<br>- Permeable to air and water vapour<br>- Lets the skin breathe<br>- Suitable for cleansing, skin prepping or as primary and secondary dressing<br>- Non sterile |
| **2.3 Intended use** | Wound cleansing, wound cover, absorption of exudates, general swabbing. |
| **2.4 Instructions for use** | Instructions for use are not necessary for class II a products. |
| **2.5 CE-class**<br>**GMDN - code** | Class IIa Rule 4<br>GMDN Code: 48133 |
| **2.6 Composition** | Cutisoft® Cotton Viskers non sterile, Typ 17 are non sterile plain woven gauze swabs/compresses made of cotton.<br><br>Swab: Woven gauze made of 100 % cotton |

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| **2.7 Latex in product and packaging material** | Product composition: No latex content<br>Packaging material: No latex content |
| **2.8 Duration of application / Period of use** | Not applicable. |
| **2.9 Phthalate in product and packaging** | No content of phthalate in product<br>No content of phthalate in packaging |
| **2.10 Controls** | **Finished product:** Weight >23 g/m²<br>Appearance White<br>Microbiological control<br><br>Acc. 5.1.4 Microbiological Quality of Pharmaceutical Preparations Category 2, European Pharmacopoeia 6, 2008 |

**2.11 Product range**

| Assortment | Size | Pieces per box | Per shipper | Product code |
|---|---|---|---|---|
| **Cutisoft® Cotton Viskers** | 180 mm x 200 mm | 100 | 60 | 71742-00 |
| **Cutisoft® Cotton Viskers** | 180 mm x 180 mm | 100 | 50 | 71742-02 |
| **Cutisoft® Cotton Viskers** | 300 mm x 300 mm | 50 | 60 | 71742-03 |

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| **2.12 Storage conditions** | Storage and transport: Dry and clean |
| **2.13 Shelf life/Storage time** | 5 years, printed on the packaging. |

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| **3.0 Safety information of Cutisoft® Cotton Viskers, non sterile, Typ 17** | |
| **3.1 Recommendations / precautions for use** | Instructions for use not necessary for class IIa product. |
| **3.2 Physical & Chemical Properties** | Combustible solid. |
| **3.3 Health Hazards** | No health hazard is anticipated during normal handling of this product. |
| **3.4 Contra Indications** | Not applicable |
| **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 Handling/ Use/ Protecting Clothing** | Not applicable. |
| **3.8 First Aid** | a) Inhalation: Not applicable<br>b) Contact with skin: Not applicable<br>c) Contact with eyes: Not applicable<br>d) Ingestion: Not applicable |
| **3.9 Disposal** | Controlled incineration/ landfill according to local environmental health guidelines. |
| **3.10 Additional Information** | Not applicable |
| **4.0 General information** | |
| **4.1 Name, address and telephone number of supplier** | BSN medical GmbH<br>Quickbornstraße 24<br>D-20253 Hamburg<br>GERMANY<br>Tel. ++ 49 40 4909-909<br>Fax ++ 49 40 4909-6666 |
| **4.2 Certificate** | EN ISO 9001 / EN ISO 13485 (notified body: Dekra) |

## History

| Version/Date | Page /Item | Description of Change |
|---|---|---|
| 01/20.10.2010 | All pages | Set up new document |
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