STERILE SWAB

Hydrophilic cotton gauze

17threads/cm² 26cmx30cm, (7.5cmx7.5cm), 12 plies,XR, Rolled, Control Tag, Double packaging, Double Box

BRIEF DESCRIPTION

Hydrophilic cotton gauze with 17 threads/cm2, total measure 26cmx30cm folded 7.5cmx7.5cm, 12 plies, with X-Ray contrast barium thread. Rolled up and packed in packs of 2 units in double packaging and box, with control tag. Sterilized by ethylene oxide.

Latex and phthalates free.

MD Class IIa according to Directive (EU) 93/42/ EEC (DL192/2023) and Regulation (EU) 2017/745 of the european Parliament and Council.

INTENDED USE

The device is intended for non-invasive use, as mechanical barrier (compression) or for absorption of exudates in daily curative procedures of chronic wounds, minor burns or other injuries with skin damage, and to control the microenvironment of surgical and non-surgical wounds, which may be superficial or deep, abrasions and surface lesions. It can also be used as a surgically invasive device for the absorption of blood and superficial body fluids, resulting from mild or deep wounds, with light to moderate drainage.

HOW TO USE

This dressing has several dimensions and different number of layers, to allow a better adaptation to the injured surface or to the surgical procedure.

For this reason it should always be used in its final fold, and should never be unfolded.

COMPOSITION

100% Cotton

INSTRUCTION SHEET

The target audience of this device is health professionals or people with relevant knowledge in the area, so given the intended use of the device, it can be used safely with-out instructions, so instruction sheets are not available with the device.

SINGLE USE DEVICE

This device is a single-use device and does not have reprocessing instructions. The risk associated to reprocessing of the product, is very high due the biological contamination of the patient, and to the impossibility of total elimination of biological material.

Using disposable items eliminates the risk of patient-to-patient contamination because the item is discarded and not used anymore.

COMPATIBILITY

The product biocompatibility is ensured by tests performed according ISO 10993, namely cytotoxicity, sensitization and irritation.

RISK ANALYSIS

Although the residual risks founded are so low that they are negligible, in the case of an invasive medical device, there is always the probability, even insignificant, of undesirable side effects like allergies. However, there is no history of side effects with this product.

EO
Sterilization by ethylene oxide

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Latex free

BPA FREE
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Physical-Chemical Characteristics

Characteristics	Method	Requirements
Number of threads/cm2 - In weave - In weft	EN 14079 Internal method (IT LAB 004) Internal method (IT LAB 004)	17 100±5 70±4
Mass(g/m2)	Internal method (IT LAB 004)	≥23
Breaking load (N) - In weave - In weft	EN 14079	 >50 >30
Sinking time (s):	EN 14079	<10
Acidity or alkalinity	EN 14079	Shouldn't dye pink
Fluorescence:	EN 14079	Negative
Extractable coloring matter:	EN 14079	Negative
Water soluble substances (%):	EN 14079	<0.5
Ether soluble substances (%):	EN 14079	<0.5
Starch and Dextrin:	EN 14079	Negative
Loss on drying (%):	EN 14079	<8
Surface-active Substances (mm):	EN 14079	<2
pH:	EN 14079	7.0+2.0
Sulphated Ashes (%):	EN 14079	Max 0.40

Microbiologic Characteristics

Aerobics Bacteria Yeasts and modulus	EN ISO 11737-2	Absence

Biocompatibility

Skin sensitization	EN ISO 10993	Does not cause skin sensitization
Skin irritation		Does not cause skin irritation
Cytotoxicity		No cytotoxicity present

Package

- Primary packaging – peel-open pack in paper and polypropylene
- Secondary packaging – Cardboard box
- Tertiary packaging – Cardboard box

Shelf-life

- The product is valid for 5 years after the date of manufacture.

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Other Characteristics

Reference	Size[1] (Open measure)	Size[1] (Closed measure)	Plies	Units/ Pack	Units/ Box
801702757512A1EO	26cmx30cm	7.5cmx7.5cm	12	2	1920

[1] Swabs present a ±10% tolerance regarding the measures.

Labelling

Primary package
(according to Directive (EU) 93/42/ EEC (DL192/2023) and Regulation (EU) 2017/745 of the european Parliament and Council).

- Medical device name
- Registered trademark
- Indication of medical device
- Identification of the package contents
- Product reference
- Lot number
- Expiration date
- Manufacturer name
- Manufacturer headquarters address
- CE marking
- Indication for single use
- Indication of the reprocessing prohibition
- Sterilization method indication

Secondary/ Tertiary package
(according to Directive (EU) 93/42/ EEC (DL192/2023) and Regulation (EU) 2017/745 of the european Parliament and Council).

- Medical device name
- Registered trademark
- Indication of medical device
- Identification of the package contents
- Product reference
- Lot number
- Expiration date
- Manufacturer name
- Manufacturer headquarters address
- CE marking
- Indication for single use
- Indication of the reprocessing prohibition
- Sterilization method indication
- GS1 Code

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PACKAGING CONDITIONS

Mixed primary packaging in paper/polyamide polyethylene film (peel-pack type) with the characteristics of these materials required in the standard EN 868.

Thermo-sealed packages on machines validated according to the requirements of EN ISO 11607.

Package with opening margin to ensure easy and correct use of the product.

The symbology presented in the packages is in accordance with the ISO 15223-1 standard.

STERILIZATION CONDITIONS

Detailed analysis of all phases of the sterilization cycle for each batch.

Check the result of the biological indicator by batch.

Execution of a sterility test carried out according to EN ISO 11737-2, at the established frequency.

STORAGE CONDITIONS

The product must be stored away from humidity at room temperature.

Temperatures between 10°C and 40°C and relative humidity between 30% and 60% are recommended.

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