Crepe Bandage

100% made in Portugal

With rotona yarn – ADA Exclusive

Intended use

This device is intended be used for support and fixation of dressing material.

How to use

The bandage is characterized by an average extensibility suitable for multiple purposes that ensure the user's comfort and allow a better adaptation to the injured surface.

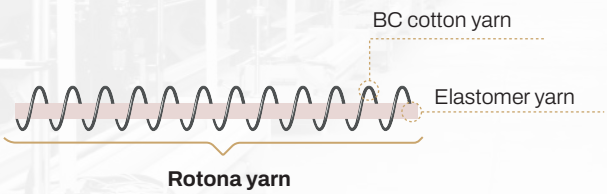
Risk Analysis

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.

Composition

98% Cotton

2% Elastane (coated with cotton.)



Brief description

Elastic cotton fabric of medium or high compression, non-adhesive and of medium extensibility, in non-sterile form. Elastomer yarn covered with cotton fibers. **The small percentage of elastane never comes into contact with the body, it is 100% covered with cotton (rotona yarn).**

Cotton from Better Cotton origin.

Air permeable (breathable) and hypoallergenic.

Latex and Phthalate free.

MD Class I according to Regulation (EU) 2017/745 of the European Parliament and Council.

Instruction Sheet

The target audience of this device is health pro-fessionals or people with relevant knowledge in the area, so given the intended use of the device, it can be used safely without instructions, so in-struction sheets are not available with the device.

Single Use Device

This device is for single use and has no reprocessing instructions. (The risk associated with reprocessing the product is very high due to the biological contamination of the patient and the impossibility of completely eliminating the biological material.)

The use of disposable items contributes to increased safety, eliminating the risk of contamination from patient to patient, as the item is discarded and not used again.

We choose sustainable cotton.
Cotton that does not compromise our planet.

Better Cotton is the world's largest organization for the sustainability of cotton production.

Its main objectives are the promotion of good practices in production, good labor relations, as well as transparency in the marketplace.

Physical-Chemical Characteristics

Characteristics	Method	Requirements
Mass (g/m2)	Internal method (IT LAB 010)	105
Elasticity (%):	Internal method (IT LAB 010)	≥ 100%
Water soluble substances (%):	Internal method (IT LAB 010)	≤ 1,0
Ether soluble substances (%):	Internal method (IT LAB 010)	≤ 1,0

Microbiologic Characteristics

Aerobics Bacteria Yeasts and modulus	EN ISO 11737-1	< 100 UFC/g

Others characteristics

Reference	Size
00105010405000	4mx5cm
00105010407000	4mx7cm
00105010410000	4mx10cm
00105010415000	4mx15cm
00105010420000	4mx20cm
00105011010000	10mx10cm
00105011015000	10mx15cm

All the determinations mentioned present a tolerance of ±8%.

Package

- Primary packaging – Polypropylene film
- Secundary packaging - Cardboard box.

Shelf-life

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

Labeling

Primary package (in accordance with Chapter III (23) of Annex I of Regulation 2017/745 of the European Commission)	Medical device name Registered trademark Indication of medical device Product reference Lot number Expiration date Manufacturer name Manufacturer headquarters address CE marking Indication for single use Indication of the reprocessing prohibition Non-Sterile indication
Secundary package (in accordance with Chapter III (23) of Annex I of Regulation 2017/745 of the European Commission)	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 Non-Sterile indication GS1 Code

Packaging conditions

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

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.

EU-MDR

This device complies with MDR requirements.