

Technical Data Sheet

DermaPlast® ACTIVE Sport Tape



Specifications: P 7.1103
Department: RD-PHSA
Date: 21/07/2017

CHANGE CONTROL REPORT

Page /Edition	Replaces Page/Edition	Reason for Change
1-2-3 from 21/07/2017	-----	New Technical Data Sheet

Department	Date	Signature
PHSA-RD, Product Developer, Gemma Galván	21/07/2017	

Technical Data Sheet

DermaPlast® ACTIVE Sport Tape



Specifications: P 7.1103
Department: RD-PHSA
Date: 21/07/2017

1. General Product Description:

DermaPlast® ACTIVE Sport Tape is a strong adhesive strapping tape made of 100% viscose with natural rubber adhesive. These tapes help to prevent painful movements by restricting the joints; can be applied directly to the skin; unroll smoothly and conform to the applied area; adhere well; and they are durable, non-elastic, firm and inductile tapes.

DermaPlast® ACTIVE Sport Tape carries the CE mark according to EU Directive 93/42/EEC for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for DermaPlast® ACTIVE Sport Tape and it has been shown to be in compliance with all the applicable requirements of the above-mentioned Directive. The safe use and effectiveness of DermaPlast® ACTIVE Sport Tape is ensured if the product is used in line with the intended purpose.

2. Application / Indication:

Intended as a sport / strapping tape for stabilizing, fixating and providing support to areas that are put under heavy stress during or after sport or other activities (such as ankle joints, knee joints, elbow joints and wrist joints).

3. Presentation:

Code	Dimensions	Dimensions of Folding box
522050	3,75 cm x 7 m (P1)	70x70x46 mm
522051	2 cm x 7 m (P1)	70x70x46 mm
522052	5 cm x 7 m (P1)	70x70x46 mm
522130	3,75 cm x 7 m (P1)	70x70x46 mm

4. Product Characteristics:

Material composition:

1	Backing material:	100% viscose, shiny, white, zig-zag edges
2	Adhesive:	Zinc oxide natural rubber adhesive, white/yellowish
3	Spool:	Polystyrene; white

Technical Data Sheet

DermaPlast® ACTIVE Sport Tape



Specifications: P 7.1103
Department: RD-PHSA
Date: 21/07/2017

5. Product requirements:

Mass per squaremeter*:	249 ± 11 g/m ²	TM00 0015-01_EN
Adhesion (steel)*:	13 ± 3 N/25mm	TM00 0090-01_EN
Unrolling force*:	11 ± 3 N/25mm	PH383/001
Bioburden:	≤ 100 cfu/g Absence of E.Coli, St, aureus, Ps.aeruginosa, Enterobacteria.	PH501/001 PH503/001

*These values are valid for the original coated roll (final product might have different values)

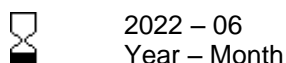
6. Labelling:

Lot-No. with 9-digit code:

LOT	X	XXX	XX	12	X
	year	No.of production order of the article	Week of the year	Plant number	Control digit

Shelf Life: The shelf life is 5 years.

Example expiry date:



7. Packaging:

DermaPlast® ACTIVE Sport Tape spools are packed in folding boxes. Boxes are packed in transport carton acc. DIN, sealed with adhesive tapes, packed onto Euro pallet.

➤ **Identification of each packaging :**

With 1 specific label with information of the product (Batch number, name of the product, expiry date, trade mark, number of boxes, code of the product).

DermaPlast® ACTIVE Sport Tape should be stored in cool and dry conditions in a good ventilated area.