Esparadrapo papel spool plasters

General Product Description/Intended Purpose

Esparadrapo papel spool plasters are non-active, single-use, self-adhesive, non-sterile devices consisting of an adhesive coated backing material (carrier material) attached to a core spool. The main constituents of this products are:

- The backing / carrier material:
  - White non-woven
- The medical grade adhesive:
  - Synthetic rubber based adhesive / Hotmelt
- Core:
  - PE Plastic spool

The products do not contain resorbable components, medicinal products / drug substances (derived from human blood or plasma or not), tissues or cells of human or animal origin, radioactive substances, nanomaterials or other hazardous components.

The products are packed in cardboard folding boxes.

Application/Indication

The main/primary function of the product is the fixation of any kind of non self-adhesive wound dressings (wound pads and traditional gauzes), bandages and tubes of cannulas, probes and/or catheters, by the adhesion properties of the device.

Reference Numbers

Packaging	Dimensions	Name	Reference number
P1	10cmx10m	Esparadrapo de papel	900696
P1	5cmx5m	Esparadrapo de papel	900697
P1	2,5cmx5m	Esparadrapo de papel	900698
P1	1,25cmx5m	Esparadrapo de papel	900699

Contra-Indications

Not indicated to be directly applied on wounds or breached / compromised skin, or for the stabilization/fixation of joints during or after sport activities (sport tape).

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

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Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

Property	Test method	Unit	Specifications
Visual examination	TM00 0001	Conform/not conform	Conform
Peel adhesion on silk	TM00 0090-02	N/25mm	11±3
Undwinding	TM00 0135-01	N/25mm	<8

Labelling

Lot-No. with 8-Digit Code
e.g.:

LOT	0	12	XXXXX
	year	week of production	for internal purposes only

Manufacturing Date

e.g.:	2020	03	01
	year	month	day

Expiry Date

e.g.:	2025	03	01
	year	month	day

Shelf Life: 5 years

Medical Device

MD

Distributor Symbol (Optional)

Latest Date of Revision: 2020-05-05