Strapping Tape / Sports Tape (e.g. Omnitape®)

Intended Purpose/General Product Description

Fixation / sport tapes are non-active, non-invasive, single-use, self-adhesive, non-sterile devices consisting of an adhesive coated backing material (carrier material) attached to a core spool.For stabilizing, fixating and providing support to areas that are put under heavy stress (joints, ligaments and muscles).

The main constituents of these products are:

- The backing / carrier material: viscose textile backing material.
- Medical grade adhesive: zinc oxide containing white adhesive (contains natural latex).
- Core: polystyrene 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 (besides natural latex in the adhesive).

The products are packed in cardboard folding boxes.

Indication

Stabilizing, fixating and providing support to areas that are put under heavy stress (joints, ligaments and muscles).

Warnings

Contains natural rubber latex which may cause allergic reactions!
Consult a doctor before applying the product if you have vascular or sensation problems (e.g. diabetic neuropathy), or if you do not know how to perform sport taping.
Remove the tape if you feel numbness or tingling during use.

Reference Numbers

Ref no.	Description	Length	Width	Content of folding box
500058	Omnitape	10m	2cm	P1
500059	Omnitape	10m	3,75cm	P1
500060	Omnitape	10m	5cm	P1

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 of our products 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 /Material Characteristics

Fabric (standard performance)				
Property	**Test method**	**Unit**	**Requirements of EN 13795 (critical reas)**	**Test results**
Visual inspection	TM00 0001	-	Not required	OK
MVTR	TM00 0188-01	g/m2/24 h		>40
Peel adhesion	TM00 0091-02	N/25mm		4 – 15 N/25mm
Tear	UNE EN ISO 13937-2	N/25mm		7 ± 3 N/25mm
Rot y elongacion MD	TM00 0096	N & (%)		(>30) & (<10)
Rot y elongacion CD	TM00 0096	N & (%)		(>50) & (<40)

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Lot-No. with 8-Digit Code

e.g.:

LOT	*0*	*15*	*XXXXX*
	year	week of production	for internal purposes only

Manufacturing Date

e.g.:	*2020*	*10*	*03*	*11:35*
	year	month	day	Hour

Use-by-Date

e.g.:	*2023*	*10*	*03*
	year	month	day

Shelf Life: 3 years

Medical Device

MD

Unique Device Indetification (UDI)

UDI

Distributor (nor for Omnitape)

Warning

Contains Latex

LATEX

Latest Date of Revision: 2020-04-16