

Omnifilm

General Product Description

Omnifilm surgical adhesive tapes are non-active, single-use, self-adhesive, non-sterile devices.

The main constituents of these products are:

- The backing / carrier material: Transparent polyethylene / PE film
- The medical grade adhesive: Acrylic adhesive
- The spool: polystyrene

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, either single spools or as multipacks.

Intended Purpose

Omnifilm is a surgical fixation tape for the fixation of any kind of non self-adhesive wound dressings (like wound pads, traditional gauzes), cannulas, probes, catheters and bandages.

The products are intended for humans, without restrictions (in age group, weight range, health status or condition), for use by healthcare professionals and lay-users, in contact with intact skin (healthy skin), and short-term ($60 \text{ minutes} \leq \text{Duration} \leq 30 \text{ days}$, acc. to MDR) / prolonged use ($24 \text{ hours} < \text{Duration} \leq 30 \text{ days}$, acc. to ISO 10993-1:2018) duration of use.

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.

Application/Indication

Omnifilm products can be cut/customized to the desired length and are tearable even without scissors.

Omnifilm

Reference Numbers

Omnifilm international range

Packaging	Dimensions	Labelling type	Name	Reference number
P1	1.25cmx5m	Folding box	Omnifilm	900433
P1	1.25cmx9.2m	Folding box	Omnifilm	900421
P1	2.5cmx5m	Folding box	Omnifilm	900434
P1	2.5cmx9.2m	Folding box	Omnifilm	900422
P12	2.5cmx5m	Folding box	Omnifilm	900630
P1	5cmx5m	Folding box	Omnifilm	900435
P1	5cmx9.2m	Folding box	Omnifilm	900423

Omnifilm Russian OTC range

Packaging	Dimensions	Labelling type	Name	Reference number
P10	1.25cmx5m	Folding box + Display	Omnifilm	900464
P10	2.5cmx5m	Folding box + Display	Omnifilm	900474
P10	5cmx5m	Folding box + Display	Omnifilm	900414

Omnifilm Spanish OTC range

Packaging	Dimensions	Labelling type	Name	Reference number
P1	2.5cmx5m	Folding box	Omnifilm	900689

Omnifilm

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.

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

Nonwoven (standard performance) 1				
Property	Test method	Unit	Requirements of EN 13795 (critical reas)	Test results
Visual inspection	TM00 0001	-	Not required	OK
MVTR	TM00 0188	g/m ² /24h		>1800
Peel adhesion	TM00 0090-02	N/25mm		9 +/- 3
Opacity	TM00 0022-02	%		<15
Unwinding	PH383/001	N/25mm		<8

Labelling

Lot-No. with 8-Digit Code

e.g.:



0

year

12

week of
production

XXXXX

for internal purposes only

Manufacturing Date

e.g.:



2020
year

03
month

01
day

00:00
Hour

Omnifilm

Use-by-Date

e.g.:  2025 03 01
year month day

Shelf Life: 5 years

Medical Device

MD

Unique Device Identification (UDI)

UDI

Latest Date of Revision: 2020-06-05