

DermaPlast® FLEXIBLE

General Product Description/Intended Purpose

DermaPlast® FLEXIBLE strips and woundplasters are non-active, single-use, self-adhesive, non-sterile devices consisting of an adhesive coated backing material (carrier material) and a woundpad, protected with a silicone paper.

The main constituents of this products are:

- The backing / carrier material:
 - Skin color elastic fabric
- The medical grade adhesive:
 - White synthetic rubber based adhesive / Hotmelt
- The wound pad with 2 different layers:
 - Exudate-transmission layer made of viscose.
 - Absorption layer of non-woven with absorbent fibers.
- Protective paper / film for the protection of the wound pad and adhesive side of the product:
 - Silicone paper

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.

Strips are sealed individually in peel-pouches and packed in cardboard folding boxes. Wound plasters are packed directly in cardboard folding boxes.

Application/Indication

DermaPlast® FLEXIBLE strips and woundplasters are non-active, single-use, self-adhesive, non-sterile devices consisting of an adhesive coated backing material (carrier material) and a woundpad, protected with a silicone paper, for the protection of minor injuries (including puncture wounds from injections) and absorption of exudate.

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

Reference Numbers

Packaging	Dimensions	Name	Reference number
P20	6x2cm 8x2cm	DermaPlast FLEXIBLE	535240
P10	6cm x 10cm	DermaPlast FLEXIBLE	535243
P10	8cm x 10cm	DermaPlast FLEXIBLE	535244

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P16	50x63 mm 20x120 mm, 45x50 mm, 38x76mm	DermaPlast FLEXIBLE Finger Mix	535245
P1	6cm x 1m	DermaPlast FLEXIBLE East SK2	535260
P1	8cm x 1m	DermaPlast FLEXIBLE East SK2	535261
P20	6x2cm 8x2cm	DermaPlast FLEXIBLE East SK1	535350

Contra-Indications

Not known.

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 Dermaplast® FLEXIBLE 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	EN ISO 5350-02	Conform/not conform	Conform
Peel test (90° peel angle)	Evaluation based on DIN ISO 6133:2017-04, procedure B	N/25mm	26 +6 -7
Absorption capacity	(DIN) EN 13726-1:2002:06	g/100cm ²	>6

Labelling

Lot-No. with 8-Digit Code

e.g.:





0

12

XXXXX

DermaPlast® FLEXIBLE

	year	week of production	for internal purposes only
<u>Manufacturing Date</u>			
e.g.: 	2020 year	03 month	01 day
<u>Expiry Date</u>			
e.g.: 	2025 year	03 month	01 day

Shelf Life: 5 years

Medical Device



Distributor Symbol



Latest Date of Revision: 2020-03-23