Technical Data Sheet

DermaPlast® TRANSPARENT

General Product Description/Intended Purpose

DermaPlast® TRANSPARENT strips 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:
  - Transparent polyethylene/PE
- The medical grade adhesive:
  - Synthetic acrylic adhesive
- 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.

Application/Indication

DermaPlast® TRANSPARENT strips 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	19x72mm 25x72mm	DermaPlast Transparentes	535742

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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® TRANSPARENT 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 (90º peel angle)	Evaluation based on DIN ISO 6133:2017-04, procedure B	N/25mm	8 +1,5 -3
Absorption capacity	(DIN) EN 13726-1:2002:06	g/100cm²	Min 900%

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 year	03 month	01 day

Expiry Date

e.g.:	2025 year	03 month	01 day

Shelf Life: 5 years

DermaPlast® TRANSPARENT

Medical Device

MD

Distributor Symbol

Latest Date of Revision: 2020-03-23