

Suprasorb® P heel

REF 180040, 180041

February 2022

1. Composition of the product

Suprasorb® P heel consists of:

Backing Film:	Polyurethane Film
Foam Pad:	Polyurethane Foam
Perforated Wound Contact Layer:	Polyurethane Film

This product data sheet covers the following items:

REF	Product description	Size (cm)
180040	Suprasorb® P heel non adhesive	13 x 10
180041	Suprasorb® P heel non adhesive LPPR	13 x 10

2. Packaging, structure and composition

2.1 Unit Container

1 piece = 1 four-edge sealed pouch made of cellulose, polyethylene and polyethylene terephthalate

2.2 Shelf Container

5 pieces = 5 four-edge sealed pouches = 1 folding box made of cellulose with instructions for use made of cellulose

2.3 Transit Container

120 pieces = 24 folding boxes = 1 corrugated cardboard box made of cellulose

3. Production

The information about production is the responsibility of the legal manufacturer (Huizhou Foryou Medical Devices Co., Ltd.).

4. Description

Suprasorb® P heel with wound contact layer consist of hydrophilic polyurethane foam and a waterproof top film with high permeability to allow effective vapor transfer. Suprasorb® P heel is soft and comfortable, has a high rate of absorbency, is water-proof and has a high permeability.

5. Properties

- moderately to heavily exuding wounds
- superficial wounds
- non-infected wounds
- for all phases of wound healing, e.g.:
 - pressure and other ulcers
 - skin graft donor sites
 - surgical wounds

6. Intended purpose/use

Suprasorb® P heel non-adhesive PU foam dressing may be used to treat chronic and acute wounds, provided they are moderately to heavily exuding and superficial.

7. Medical device classification

Suprasorb® P heel is a Class IIb medical device according to Rule 4 (according to directive 93/42/EEC for medical devices).

8. Biological assessment and compatibility

The information about biological assessment and compatibility is the responsibility of the legal manufacturer (Huizhou Foryou Medical Devices Co., Ltd.)

9. Shelf life

~~Stored appropriately (store in a dry and shady place with room temperature)~~
Suprasorb® P heel has a shelf life of 3 years from the date of manufacture.

10. Disposal

The user has to observe the applicable national laws, standards and guidelines for the disposal of waste from the medical sector.

National requirements also have to be taken into account when disposing of packaging materials.

11. Legal manufacturer:

The following legal manufacturer hereby confirms the accuracy of the information provided in this product data sheet:

Legal manufacturer:

Huizhou Foryou Medical Devices Co., Ltd.
No.1 Shangxia North Road
Dongjiang Hi-tech
Industrial Park
516005, Huizhou
P.R. China

Distributor:

Lohmann & Rauscher GmbH & Co. KG
Westerwalstraße 4
56579 Rengsdorf
Germany

 2022.2.8

Date, Signature



Peter.Grillitsch@sal.LRMed.com, Feb 8, 2022 11:40:19 AM UTC

Date, Signature

EC-REP:

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