

Porofix® Adhesive Tape

REF 143870 - 143875

October 2022

1. Composition of the product

Porofix® Adhesive Tape consists of:

- cotton
- glue (Hot melt adhesive containing zinc oxide)

This product data sheet covers the following items:

REF	Product description	Size	Feature
143870	Porofix® adhesive tape	1,25 cm x 5 m	Plastic core, with ring
143871	Porofix® adhesive tape	2,5 cm x 5 m	Plastic core, with ring
143872	Porofix® adhesive tape	5 cm x 5 m	Plastic core, with ring
143873	Porofix® adhesive tape	1,25 cm x 9,2 m	Paper core
143874	Porofix® adhesive tape	2,5 cm x 9,2 m	Paper core
143875	Porofix® adhesive tape	5 cm x 9,2 m	Paper core

2. Packaging, structure and composition

2.1 Unit container

REF 143870-143872

1 Unit = on polystyrene spool and protective

REF 143873-143875 see 2.2

2.2 Shelf container

1 folding box consisting of cellulose

On plastic core with ring:

REF	pcs.
143870	18
143871	12
143872	6

On paper core:

REF	pcs.
143873	24
143874	12
143875	6

2.3 Transit container

1 corrugated cardboard box (cellulose)

REF	pcs.	Folding boxes
143870	450	25
143871	336	28
143872	150	25
143873	720	30
143874	360	30
143875	180	30

3. Manufacture

The information about production is the responsibility of the legal manufacturer:

Zhende Medical co., Ltd
Gaobu Town
312035 Shaoxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

4. Description

Porofix® Adhesive Tape are light-brown, air and water Vapour permeable adhesive tapes.

5. Properties

- non-elastic
- skin-friendly
- fast and reliable adhesion
- water-repellent

6. Intended purpose

Porofix® Adhesive Tape is intended for infusion tube fixation, wound dressing fixation and medical supplies fixation. They are mainly used by professional physicians, nurses or family members in hospitals, clinics or homecare.

7. Medical device classification

Porofix® Adhesive Tape is a medical device of class I according to rule 1.
(Council Directive 93/42/CEE and Regulation 2017/745)

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The information about biological assessment and compatibility is the responsibility of the legal manufacturer:

Zhende Medical co., Ltd
Gaobu Town
312035 Shaoxing, Zhejiang
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9. Requirements regarding the safety/harmlessness of the constituents

According to the supplier's information, there are no ingredients of concern.

10. Stability

Stored appropriately – keep dry, in cool and clean area, the humidity is lower than 80%, temperature is between 0°C and 40°C, without corrosive gas – Porofix® Adhesive Tape has a shelf life of 3 years from manufacturing date.

11. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.
Packaging materials must also be disposed of in compliance with applicable national requirements.

12. Legal manufacturer:

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

Legal manufacturer:

**Zhende Medical Co. Ltd
Gaobu Town
312035 Shaoxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA**

Distributor:

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



2022.10.27

Date, Signature

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