

## Silkafix® Adhesive Tape

REF 143853 - 143859

October 2022

### 1. Composition of the form of application (product)

Silkafix® Adhesive Tape is composed of:

- 100% acetate silk
- glue (acrylic adhesive)

This product data sheet applies to the following products:

REF	Product description	Size	Feature
143853	Silkafix® Adhesive Tape	1.25 cm x 5 m	Plastic core with ring
143854	Silkafix® Adhesive Tape	2.5 cm x 5 m	Plastic core with ring
143855	Silkafix® Adhesive Tape	5 cm x 5 m	Plastic core with ring
143856	Silkafix® Adhesive Tape	2.5 cm x 5 m	Paper core
143857	Silkafix® Adhesive Tape	1.25 cm x 9.2 m	Paper core
143858	Silkafix® Adhesive Tape	2.5 cm x 9.2 m	Paper core
143859	Silkafix® Adhesive Tape	5 cm x 9.2m	Paper core

### 2. Composition / structure of the packaging

#### 2.1 Unit container

REF 143853, 143854, 143855

1 Unit = 1 polystyrene spool  
polystyrene protective ring

REF 143856, 143857, 143858, 143859

see 2.2

## 2.2 Shelf container

1 folding box consisting of cellulose

On plastic core with ring:

REF	pcs.
143853	18
143854	12
143855	6

On paper core:

REF	pcs.
143856, 143858	12
143857	24
143859	6

## 2.3 Transit container

1 corrugated box, made of cellulose:

REF	pcs.	Folding boxes
143853	450	25
143854	336	28
143855	150	25
143856	300	25
143857	480	20
143858	240	20
143859	120	20

## 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

Silkafix® Adhesive Tape is a product of a white acetate fabric coated adhesive, cut with serrated knives and wound on a plastic or paper core.

## 5. Properties

- tearable lengthwise and widthwise
- non-elastic
- skin-friendly

- adhesive adheres well to the skin yet leaves little residue when removed
- water- and dirt-repellent

## **6. Intended purpose / use**

Silkafix® Adhesive Tape is intended to be used 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. Classification**

Silkafix® 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**

(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  
PEOPLE'S REPUBLIC OF CHINA

## **9. Requirements regarding the safety/harmlessness of the constituents**

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

## **10. Shelf life**

Silkafix® Adhesive Tapes should be stored in a cool clean room and no corrosive gas, free from direct sunlight. The product has a shelf life of 3 years.

## **11. Disposal**

The user must observe the relevant national laws, standards and guidelines regulating the disposal of medical waste.

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

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Date, Signature

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Date, Signature