

Peha-fix®



Spec.-No.: D 2.5410-01

Department: PMI - KOB

Date: 28.05.2018

1. General Product Description

Peha-fix® is a highly-elastic conforming bandage acc. DIN 61 634-FB, **consisting of a softly special fabric with a high proportion of natural fibers, elasticity approx. 125 %; quick and easy to apply without reverse turns to secure the bandage; reliable non-slip dressing retention; may be sterilized; for single use only; white.**

Peha-fix® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for **Peha-fix®** and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of **Peha-fix®**, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Dressing retention, especially on joints and conical or rounded parts of the body.

3. Presentations

Dimensions	Unit	Units per Case
individually wrapped in PP-foil		
4 cm x 4 m (stretched length)	OP 1 bandage	20/160 OP
6 cm x 4 m (stretched length)	OP 1 bandage	20/200 OP
8 cm x 4 m (stretched length)	OP 1 bandage	20/200 OP
10 cm x 4m (stretched length)	OP 1 bandage	20/120 OP
12 cm x 4 m (stretched length)	OP 1 bandage	20/80 OP
in cardboard box		
4 cm x 4 m (stretched length)	AP 20 bandages	8 AP
6 cm x 4 m (stretched length)	AP 20 bandages	10 AP
8 cm x 4 m (stretched length)	AP 20 bandages	10 AP
10 cm x 4m (stretched length)	AP 20 bandages	6 AP
12 cm x 4 m (stretched length)	AP 20 bandages	4 AP
in compact packing		
6 cm x 4 m (stretched length)	AP 100 bandages	8 AP
8 cm x 4 m (stretched length)	AP 100 bandages	6 AP
10 cm x 4 m (stretched length)	AP 100 bandages	6 AP
12 cm x 4 m (stretched length)	AP 100 bandages	4 AP

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4. Product Characteristics

Material: 70 % Viscose
30 % Polyamide

Construction: knitted fabric
elastic bandage with fast edges

5. Product Requirements

Elongation: Approx. 125 %

Mass per square meter, stretched: Approx. 27 g/m² stretched

6. Labelling

Lot-No. with 8-digit code:
e.g.:

5
year

50
calendar week

XXXXX
for internal purposes only

Shelf life: 5 years

7. Packaging

Peha-fix® individually wrapped in PP-foil and packed in folding box;
or:
Peha-fix® bandages packed in cardboard box;

Transport carton acc. DIN, sealed with adhesive tapes, packed onto euro pallet.

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- Department Product Management & Innovation (PMI-KOB) -