

Idealflex®



Spec.-No.: D 2.6772

Department: KOB

Date: 2007-01-31

CHANGE CONTROL REPORT

Page /Edition	replaces Page/Edition	Reason for Change
1-2 dated 2007-01-31	new	New Technical Data Sheet

Department	Date	Signature
KOB Development	2007-01-31	<i>J. Nille</i>

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1. General Product Description

Idealflex® is a permanently elastic multipurpose short-stretch bandage, elasticity approx. 90%; kind to the skin; may be washed at 60°C and sterilized (steam 134°C), natural white.

Idealflex® 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 **Idealflex®** and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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

2. Application / Indication

For moderate compression; as a support and relief bandage in musculo-skeletal injuries; as a sports bandage; as a dressing retention bandage with compression effect, for securing splints.

3. Presentations

Dimensions	Unit	Units per case
individually wrapped in polypropylene film, packed in cardboard boxes, without bandage clips		
6cm x 5m (stretched length)	AP 10 bandages	8 AP
8cm x 5m (stretched length)	AP 10 bandages	6 AP
10cm x 5m (stretched length)	AP 10 bandages	5 AP
12cm x 5m (stretched length)	AP 10 bandages	4 AP
15cm x 5m (stretched length)	AP 10 bandages	3 AP
20cm x 5m (stretched length)	AP 10 bandages	2 AP
individually packed in cardboard boxes, without bandage clips		
6cm x 5m (stretched length)	AP 10 bandages	8 AP
8cm x 5m (stretched length)	AP 10 bandages	6 AP
10cm x 5m (stretched length)	AP 10 bandages	5 AP
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4. Product Characteristics

Material composition: 45% polyester, 42% cotton, 13% viscose
Construction: plain weave
elastic bandage with selvedge

5. Product Requirements

Extensibility: ca. 90%
(lengthwise direction)
Widths of bandage: 6, 8, 10, 12, 15, 20 cm
Length stretched: ca. 5 m
Weight/m² stretched: ca. 85 g/m²

6. Labelling

Lot-No. with 7-digit code:

e.g.:

LOT	07	05	3	XX
	year	week of production	day	for internal purposes only

Shelf life: 5 years

7. Packaging

Idealflex® individually wrapped in polypropylene film, packed in folding boxes, transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

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