

Idealhaft®



Spec.-No.: D 2.6741
 Department: **SM-PDC**
 Date: 2007-01-10

CHANGE CONTROL REPORT

Page /Edition	replaces Page/Edition	Reason for Change
1-2 dated	-----	New Technical Data Sheet
1-2 dated 2006-10-26	dated 1999-09-02	revision
1-2 dated 2007-01-10	dated 2006-10-26	revision

Department	Date	Signature
Product Development SM-PDC	2007-01-10	<i>Eric Berndt</i>

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1. General Product Description

Idealhaft® are cohesive, short-stretch cotton crepe bandages with textile elasticity of approx. 60 %; cohesive effect on both sides of the bandage for perfect fit; high working pressure with light resting pressure; may also be worn when the patient is in a resting position, permeable to air; may be sterilized (steam A 134°C); radiotransparent; skin-coloured.

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

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

2. Application / Indication

For extra high compression; in chronic venous obstructive oedema, healed leg ulcers, thrombophlebitis, for follow-up treatment of venous disorders and in knee phleboarthrosis; as a support and relief bandage in musculo-skeletal injuries; as a sports bandage.

3. Presentations

Dimensions	Unit	Units per Case
individually boxed		
6cm x 5m (stretched length)	OP 1 bandage	60 OP
8cm x 5m (stretched length)	OP 1 bandage	40 OP
10cm x 5m (stretched length)	OP 1 bandage	40 OP
12cm x 5m (stretched length)	OP 1 bandage	30 OP
individually boxed		
20cm x 7m (stretched length)	OP 1 bandage	12 OP

4. Product Characteristics

Material composition: 100% cotton
with special latex coating

Construction: plain weave
elastic bandage with cut selvedge

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5. Product Requirements

Extensibility: approx. 70%
Widths of bandage: 6; 8; 10; 12; 20 cm
Length of bandage (stretched): 5 m; 7 m
Weight/m² stretched: approx. 165 g/m² coated

6. Labelling

Lot-No. with 7-digit code:

e.g.:

06
year

43
week of production

XXX
for internal purposes only

Expiry date:

e.g.:  2009-10
year month

Shelf life: 3 years

7. Packaging

Idealhaft® individually packed in folding boxes, transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

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