

Veno 4



Spec.-No.: D 2.6855a

Department: TME-B

Date: 2005-02-09

CHANGE CONTROL REPORT

Page /Edition	replaces Page/Edition	Reason for Change
1-2 dated 2005-02-09	new	New Technical Data Sheet

Department	Date	Signature
Technical Medical Development (TME - B)	2005-02-09	<i>S. Hech</i>

Veno 4



Spec.-No.: D 2.6855a

Department: TME-B

Date: 2005-02-09

1. General Product Description

Veno 4 is a latex-free four-layer compression bandage system, suitable for most patients with venous leg ulcers. When applied correctly, Veno 4 can provide compression for up to seven days.

Veno 4 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 Veno 4 and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Veno 4, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Veno 4 is used to manage chronic venous insufficiency and related conditions.

3. Presentations

For ankle circumference 18-25 cm;

Set consisting of:

- 1 Natural padding bandage 10 cm x 3.5 m (unstretched)
- 1 Cotton Crepe bandage 10 cm x 4.5 m (stretched)
- 1 Latex-free light elastic compression bandage 10 cm x 8.7 m (stretched)
- 1 Latex-free cohesive support bandage 10 cm x 6.0 m (stretched)
- 1 instructions for use

Unit of sale: Single, Box of 5, Carton of 30

4. Product Characteristics

Veno 4 consists of four latex-free bandages:

- Layer 1, padding bandage – absorbs exudate and redistributes pressure around the bony prominence of the ankle.
- Layer 2, cotton crepe bandage – smoothes padding bandage.
- Layer 3, light elastic compression bandage – conforms to leg contours. Classified as a Type 3a light compression bandage by BS 7505:1995 this will deliver 17 mmHg.
- Layer 4, cohesive bandage – adds to compression effect and helps keep the bandages in place for up to seven days. A Type 3a light compression bandage. When applied at mid stretch with a 50% overlap, this bandage gives an ankle pressure of 23 mmHg.

All bandages are non sterile, if necessary, layer 1, layer 2 and layer 3 can be sterilized in the autoclave at maximum 121° for 20 minutes. All packaging material must be removed before sterilization.

Veno 4



Spec.-No.: D 2.6855a

Department: TME-B

Date: 2005-02-09

5. Product Requirements

Layer 1	viscose	padding bandage
Layer 2	cotton, viscose, polyamide	light supporting bandage lengthwise elastic BS 7505 Type 2
Layer 3	viscose, cotton, polyamide, spandex	light compression bandage lengthwise elastic BS 7505 Type 3a latexfree
Layer 4	polyester, spandex	cohesive compression bandage lengthwise elastic BS 7505 Type 3a latexfree

6. Labelling

Lot-No. with 7-digit code:

e.g.:

9
year

44
week of production

XXXX
for internal purposes only

Expiry date:

e.g.: ⌚ 2008 06
year month

Shelf life: 3 years

7. Packaging

Each of the four bandages of the Veno 4 kit is individually packed into polypropylene foil. The bandages and the instructions for use are put into a polyethylene bag with zipper, transport carton acc. DIN, sealed with adhesive tapes, packed onto pallet.

Date: 2005-02-09

