

# PRODUCT DATA SHEET

**4-m long Tubular Bandages**  
**REF: 14799 – 14806, 14814, 14815**

**25-m long Plain Stockinettes**  
**REF: 14820 - 14826**

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Translation: C.M.Kelly/VW

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## 1. Composition of the product

The above tubular bandages and stockinettes are knitted tubes which consist of:

- 100 % cotton

The stockinette REF 92850 complies with the current edition of specification no. SP 28-00060-.. "Trikotschlauchbinde, Trikotschlauch" and is identical to REF 14824 specified thereon.

## 2. Packaging, structure and composition of:

REF: **14799 - 14806**

REF: **14820 - 14826**

REF: **14814, 14815**

2.1.

### Unit Container

- polyethylene bag

- polyethylene bag
- polyethylene clip, red

- see 2.2

2.2.

### Shelf Container

- see 2.3.

- see 2.3.

- polypropylene core
- polyethylene bag

2.3.

### Transit Container

- corrugated cardboard case (cellulose)

## 3. Manufacture

The tubular bandages and stockinettes are produced on a circular knitting machine in plain jersey construction with a 100 % cotton yarn. The finished products are placed individually in transparent polyethylene bags and packed for transportation in corrugated cardboard cases.

4. Description

Seamless, close-meshed knitted tubes, plain jersey construction, produced with an off-white cotton yarn, 4 m and 25 m long. Available in several widths.

5. Properties

The above tubular bandages and stockinettes are highly conformable and non-irritant. They are extensible in the width and economical in use.

The material possesses the elasticity typical for knitwear, above all in the width. The tubular bandages and stockinettes can be sterilized by steam according to EN 554.

6. Intended purpose

The tubular bandages and stockinettes are intended for use as a protective device under casts as well as for the retention of wound dressings.

7. Medical device classification

Used primarily for protection under casts and intended to come into direct contact with healthy skin only Rule 1 Annex IX of the Council Directive 93/42/EEC concerning medical devices applies:

**The tubular bandages and plain stockinettes are Class I products.**

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

For undercast protection, for dressing retention.

The tubular bandages and stockinettes are intended to have direct contact with healthy and unscarified skin only.

Cotton is traditionally the raw material for many surgical dressings and as such is described as their main component of several monographs in national and international pharmacopoeia.

Cotton is known to be pharmacologically harmless and indifferent. Because of its excellent biocompatibility cotton is also widely used in the textile industry manufacturing underwear.

The starting material used to produce the above tubular bandages and stockinettes is of such purity that the use of these products is considered safe providing they are used as intended.

To date this company has received no notification of incidents involving these Lohmann & Rauscher products, neither has there been a need for a re-call for reasons of quality.

The purpose of this documentation and of the statements made therein is to show that there is no risk involved in the use of the above tubular bandages and stockinettes, and that - as it says in the Essential Requirements of the Council Directive 93/42/EEC concerning medical devices – the tubular bandages and stockinettes " are designed, manufactured and packaged in such a way that they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons when used under the conditions and for the purposes intended".

9. Stability

Stored appropriately the above tubular bandages and stockinettes have a minimum shelf life of 5 years.

10. Disposal

Incineration or landfill disposal of the above tubular bandages and stockinettes and their packaging will generate only CO<sub>2</sub> and H<sub>2</sub>O.

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signed by  
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(Medical & Regulatory Affairs)