

# POROTAPE® Adhesive Tape

## REF 30081 - 30084

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### 1. Composition of the product

POROTAPE® Adhesive Tape consists of:

- Viscose
- Rubber adhesive containing zinc oxide (contains natural rubber latex)

This product data sheet covers the following items:

REF 30081	Porotape®	2.5 cm x 10 m	1 carton (6 pcs.)
REF 30082	Porotape®	3.8 cm x 10 m	1 carton (12 pcs.)
REF 30083	Porotape®	5.0 cm x 10 m	1 carton (6 pcs.)
REF 30084	Porotape®	3.8 cm x 10 m	1 carton (1 pcs.)

### 2. Packaging, structure and composition

#### 2.1 Unit container

see 2.2

#### 2.2 Shelf container

- polypropylene core
- cellulose folding box

#### 2.3 Transit container

- corrugated cardboard box (cellulose)

### 3. Manufacture

POROTAPE® is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

#### **4. Description**

POROTAPE® is an off-white adhesive tape with serrated edges, wound on a plastic core. The adhesive tape made of viscose is coated on one side with a rubber adhesive containing zinc oxide.

#### **5. Properties**

Non-elastic adhesive tape, high tensile strength, can be torn length- and widthwise, with a strongly adherent zinc oxide rubber. POROTAPE® is applied both on skin, but mainly in combination with adhesive bandages. It is intended for the part-immobilization of limbs, giving support to and relieving strain on joints, sinews, muscles and ligaments. It can also be used for the prophylactic strapping of particular parts of the body with the aim of avoiding excessive strain developing in such places. The adhesive tape is easy to unroll and the serrated edges facilitate separating individual pieces from the roll; they also guard against threads coming off.

#### **6. Intended purpose**

POROTAPE® is used for partial immobilisation providing support and pressure relief for joints, tendons, muscles and ligaments as well as for prophylactic bandages for the prevention of overexertion and injury.

#### **7. Medical device classification**

POROTAPE® is a medical device of Class I in terms of Rule 1.  
(Council Directive 93/42/EEC concerning medical devices, Annex IX)

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

The starting materials used in the manufacture of POROTAPE® are safe if the product is used appropriately and for the purposes intended.

Persons who are allergic to zinc, zinc compounds or natural rubber latex should avoid having POROTAPE® applied to the unprotected skin.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device POROTAPE® and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

#### **9. Stability**

Stored appropriately, POROTAPE® has a shelf life of 5 years.

## **10. Disposal**

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.

Packaging materials must also be disposed of in compliance with applicable national requirements.

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signed by

Dr. Martin Abel

(Medical & Regulatory Affairs)