

## INFORMATION LEAFLET - COTTON WOOL MEDICAL DEVICE

### DECLARATION OF CONFORMITY

A conformity declaration, issued in accordance with the requirements of current legislation in the European territory, can be provide upon request.

### MANUFACTURER'S DETAILS

**Company name :** Turati Idrofilo S.p.A.

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**Vat number:** 07243840019

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**Website :** [www.turati-idrofilo.com](http://www.turati-idrofilo.com) e [www.cottonplus.it](http://www.cottonplus.it)

### AUTHORIZED ASSISTANCE

For technical assistance on the product, you can contact the manufacturer using one of the above contact details. Technical assistance on the product can and should be carried out only by Turati Idrofilo S.p.A.

### PRESENTATION OF THE LEAFLET

This leaflet contains instructions regarding the use of absorbent cotton as an aid in daily dressing activities that does not come into contact with damaged skin or mucosa.

This leaflet is intended for the person in charge of the use and storage of the medical device and is related to the product.

This leaflet contains proprietary information and may not be even partially replicated for any use and in any form without the prior written consent of the manufacturer.

Turati Idrofilo S.p.A. declares that the information contained in this package leaflet is congruent with the technical and safety specifications of the medical device to which the leaflet refers.










A true copy of this leaflet is contained in the technical file of the device, which is kept at Turati Idrofilo S.p.A.

Turati Idrofilo S.p.A. does not recognize any documentation that has not been produced, issued or distributed by itself or its authorized representative.

Translated with DeepL.com (free version)

### SYMBOLS

Other symbols, in addition to those listed, could be added.

|   |                |   |   |
|---|----------------|---|---|
|  | CE mark        |  | Keep dry . Protect the medical device from wet and weathering |
|  | Manufacturer   |  | Keep away from sunlight                                       |
|  | Lot number     |  | Non-sterile   |
|  | Medical Device |  | Expiring date   |
|  | Do not re-use  |   |   |

### MEDICAL DEVICE DESCRIPTION

Items of various sizes and weights made of 100% absorbent cotton, carded and/or water-treated in accordance with the European Pharmacopoeia.

It is recommended to read this leaflet carefully before using the medical device.

#### **TECHNICAL DATA**

Material: 100% cotton

#### **FIELD OF APPLICATION AND INTENDED USE**

Non-invasive device for use as an aid in daily dressing activities that is not placed in contact with injured skin or mucosa.

#### **UNINTENDED USE**

No use other than those described in the paragraph "FIELD OF APPLICATION AND INTENDED USE" is intended.

- It is also absolutely forbidden:
- Use by persons allergic to cotton.
- Use by children.
- Use by individuals with limited cognitive abilities.

#### **LIMITATIONS OF THE MEDICAL DEVICE**

- Absorbent cotton does not cure any disease.
- The medical device can only be used once as it is disposable.

#### **RESIDUAL RISKS.**

- It is absolutely forbidden to make any modifications to the medical device. Any damage resulting from the use of the device, improperly modified by an unauthorized operator, relieves the manufacturer of all liability.
- Carefully keep this manual, which is necessary for the proper and safe use of the medical device.
- If the packaging shows breaks that could contaminate the device and make it unusable, we suggest informing the retailer.

#### **SIDE EFFECTS**

**There are no side effects to report in the instruction manual.** However, do not apply the product to the skin when there is an open wound or irritation. In case of irritation caused by the product, stop application immediately and consult a doctor to check for cotton allergy.

#### **CONTRAINDICATIONS**

The medical device may cause irritation on individuals who are particularly sensitive or allergic to cotton material.

#### **STORAGE**

- Store the medical device indoors cool and dry, away from weather and steam jets.
- Store the medical device away from heat sources, open flames and direct sunlight.
- Store the medical device, before use, inside its original packaging.

#### **USE**

- Sanitize hands by washing them thoroughly with soap and water before use
- Take cotton and if necessary dip it in a disinfectant and/or similar substances.
- Gently dab the affected body part.
- Disposable
- Non-sterile

#### **WARNINGS**

- AVOID IMPROPER USE
- DO NOT USE ON INJURED SKIN.
- DO NOT SWALLOW.

#### **AGE OF ELIGIBILITY FOR USE ON CHILDREN**

The medical device can be used on children zero years of age and older.

#### **DISPOSAL**

After use, cotton should be disposed of in general waste.

If there are traces of polluting and/or potentially hazardous materials and/or substances in the cotton, dispose of it in biohazardous special waste.

Plastic packaging (LDPE4) can be disposed of in plastic recycling.

Check your local disposal regulation

Do not disperse or abandon the product and packaging in the environment for any reason. Never make the packaging available to children (individuals under 14 years of age).