

# **TECNIC CAPITOL "Toothbrush Whitening"**

## **TECHNICAL FEATURES OF THE MATERIAL:**

The material used for the bleaching thimble is an elastomer polymer that can be classified within the world of TPE (Thermoplastic elastomer) on a SEBS basis (Stirene-ethilene-butadiene -stirene) un reticulated (non-volcanic).

In addition to SEBS, the formulation has a PP-based polypropylene polyometric (polypropylene) polyometric matrix, a substantial presence of pharmaceutical oil as well as antioxidants and process-aids.

## **TOOTHBRUSH WHITENING DEVICE FUNCTIONALITY:**

The first action carried out with the use of the bleaching thimble is mechanical; the material characterized by a strong grip, does not scratch the teeth, but performs a cleaning action aimed not only at the possible residues of food left between the teeth, but the entire hygiene of the oral cavity.

The formulation of the material allows to massage and clean also gums, tongue and pal showing, with regular use, to be effective in removing stains on teeth due to unhealthy habits (smoke, alcohol, coffee).

The mechanical action related to the use of the bleaching thimble (massage-rubbing), as well as chewing, causes an increase in salivation, which thanks to its performance of buffer solution, raises the pH above the acidic area, unfavorable to life and bacterial proliferation in the plaque.

The remarkable mechanical strength provided by the material used (based on SEBS with a very high molecular weight) guarantees a number of at least 100 uses without the possibility of detachments of small parts or breaks.

The presence of white kaolina (white clay) allows a greater effect of polishing the tooth making the enamel more reflective.

This clay has no abrasive character due to its particular geometry.

The function of titanium dioxide is purely related to the coloring of the print.

The presence of menthol and food aromas provides a pleasant sensory appearance of the product, that can refresh the breath during and after the action of rubbing

## **BLEACHING DITALE FORMULATION (S, M):**

POLYMER MED +PURE MENTHOL+ FOOD AROMAS+ WHITE KAOLINA + DYE FOR COSMETIC USE (used as a dye)

The ingredients of the compound are weighed manually and gravimetrically dosed in a twin screw extruder of sufficient length to obtain a perfect mixing and amalgamation of all ingredients. Currently an extruder is used in the gray room.

The compound is checked and characterized according to the regulations indicated in the datasheet (on request)

Attached to this document all the safety cards of all materials used for the construction of the compound.

## **ADDING FRAGRANCE**

Before being printed or extruded, the compound is added to natural or synthetic fragrances for food use to attribute different sensory aspects to finished products.

The compound for the bleaching thimble is added to a maximum of 4% (w/w %) pure menthol in crystals, lemon extract, sage extract in olive oil (TDS and MSDS attached to the file).

## **CERTIFICATIONS:**

The compound complies with the most stringent international (ISO) and American (USP) regulations, as it is able to comply with the regulatory requirements for materials used for medical applications, thanks to the attached documentation.

The compound, from the POLYMER MED family, is commonly proposed and used in medical devices, up to implantability.

The compound is produced in a controlled environment in accordance with ISO 10993-4 and 5.

The compound has been successfully tested under the following ISO and USP regulations.

## ITALIAN STANDARD:

Ministerial Decree of 21 March 1973 subsequently amended as follows:

- ☐ D.M. del 26-04-1993 n°220,
- ☐ D.M. del 24-09-1996 n°572,
- ☐ D.M. del 22-07-1998 n°338,
- ☐ D.M. del 15-06-2000 n°210,
- ☐ D.M. del 28-03-2003 n°123,
- ☐ D.M. del 18-04-2007 n°82.

## STANDARD INTERNATIONAL “ISO”:

- UNI EN ISO 10993-4 TEST EMOLISI;
- UNI EN ISO 10993-5 TEST CITOTOSSICITA’;

-Regulation (CE) Nr. 1935/2004 European Parliament and the European Council of 27/10/2004 materials and items intended to come into contact with food products, referred to in the previous Directive 2002/72/CE and the Rules 10/2011 are a specific measure under art. 3.

-Regulation (CE) Nr. 2023/2006 Commission of 22/12/2006 good manufacturing practices of materials and objects intended to come into contact with food products.

## STANDARD GERMANY:

B.G.V.V. (ex B.G.A.) as shown below “Empfehlung XXI”: “Synthetic tyres”.

## STANDARD U.S.A. “USP”:

Test	Test Report N°	Test methods and other normative references
Intracutaneous reactivity test in the rabbit	18-0681-01	USP XXXVI-NF31 1st Supplement 2013 <88>
Acute systemic toxicity test in the mouse	18-0681-02	USP XXXVI-NF31 1st Supplement 2013 <88>
Implantation test in the rabbit	18-0681-03	USP XXXVI-NF31 1st Supplement 2013 <88>
Haemolysis test	18-0681-04	ISO 10993-4:2017; ISO 10993-12:2012; ASTM F756-17

FDA: CFR (Code of Federal Regulations) :

Chapter 21 §177.1810 “Styrenic block polypolymers”;

Chapter 21 §177.1520 “Olefinic polymers”;

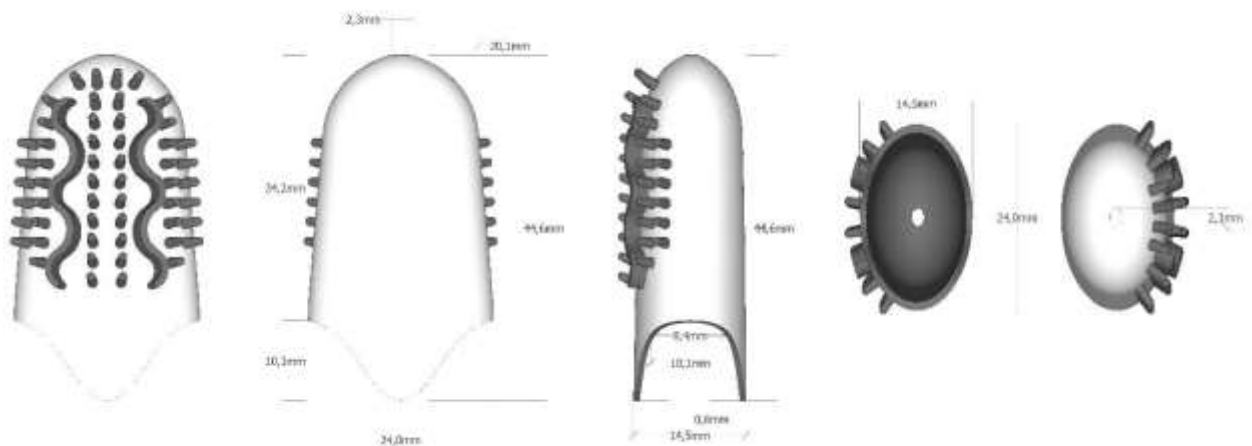
Chapter 21 §177.2600 “Rubber items for repeated use” prior verification by divestment test.

### CONTROL IN PRODUCTION:

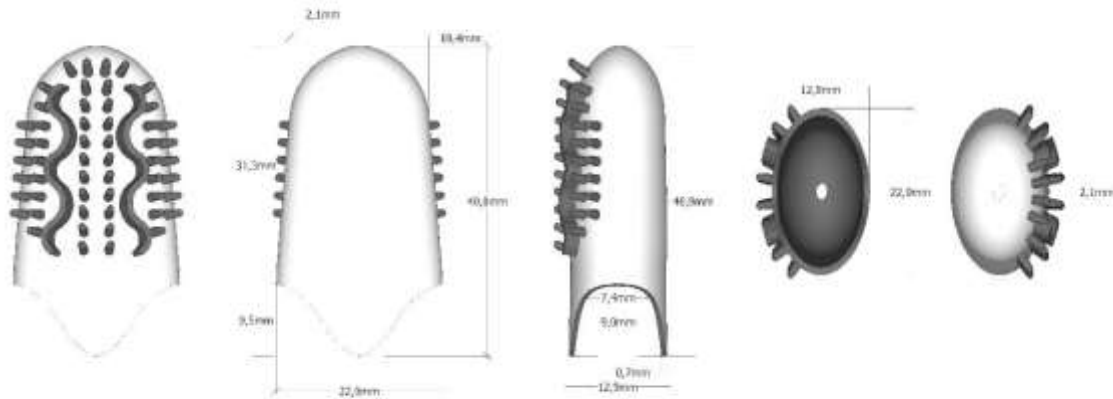
Each measure of the bleaching thimble is described by a quoted technical design:



Size M:



Size S:



TrueFalsi: demand to carlo.malegouster - malegouster@dentalsmilesolutions.com

The handouts, at the beginning of production (start), are dimensionally compared with the related technical drawings (above, for example, the technical drawings of the bleaching thimble).

The visual appearance (color and homogeneity) is compared with a reference sample.

Only if the visual appearance and dimensional values are positively confirmed then the start-up phase ends and the production phase begins.

During production each individual printout is visually checked and bagged in its polyethylene envelope, in groups of 200/250 pieces. The 200/250-piece envelopes are then packed into larger envelopes in HDPE in order to limit the evaporation of the fragrances, and finally boxed with its label identifying production lot and product code.

### CONTROL DURING PACKING:

At "XXX" the molding (production) phase takes place in accordance with GMP regulations.





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At "XXX" takes place, the quality control and the insertion of the thimble inside the box in the gray room.

### **QC DURING PACKING:**

At "XXX" the packing phase takes place.

Each individual piece is visually checked in appearance and size (S, M) before being placed in the appropriate box.

The box also undergoes a quick visual check during production and packaging. The box is made of food-contact-dedicated polypropylene.

Any black point, impurity, chromatic fluctuation, particulate matter inside or on the surface of the prints (bleaching thimble and box), visible to the naked eye, must be, both in production and packaging, scrapped and archived in order to perform a % assessment of the deviation incidence at the end of the process (the extent of the defect is therefore not described as passable or non-passable). Any defect of any entity or visibility has to be considered waste.

Any imperfection that goes beyond quality checks does not pose any danger to the user or malfunction of the product.

Each item is followed by its own code from production to delivery to the distributor.

Each individual sachet (containing the bleaching thimble) has a daily alphanumeric code showing the Julian day.

This daily subdivision allows, in the event of complaints by the user, to trace the individual offending lot, withdrawing a limited quantity of products from the market.

Finally, Dental smile solutions, performs statistical checks on the finished product to ensure its quality before distribution according to AQL methodology as agreed with the final manufacturer.

All the safety sheets of the individual ingredients and fragrances used, the compound's safety sheet, are available as attachment to this file.