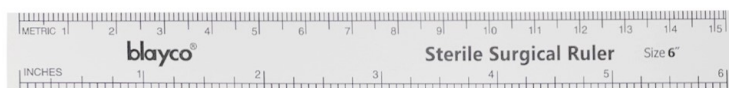


Skin marker

Blayco

> Product description

The skin marker is a medical device used to mark the skin of the patient before or during surgical procedure.



> Product characteristics

- Colour of ink: Gentian violet.
- Solvents of ink: isopropyl alcohol and water.
- Washing agent: water, alcohol (ethanol).
- Width of marking:
 - TCH02TO: standard tip 1 mm.
 - TCH05TO: dual-tip (standard 1 mm and thin tip 05 mm).

> Technical specifications

> Materials

- Body: Polypropylene.
- Cap and cover: Polypropylene.
- Rule: Plasticized Paper + Film
- Nib: Synthetic fibre.
- Ink: Gentian violet (CAS n. 548-62-9).
- Pouch: PET / PE film and medical grade sterilizable paper.

> Main dimensional properties

- Length of skin marker (including cap): 16.5 cm (Reference TCH2TO).
- Length of skin marker (including caps): 14cm (Reference TCH5TO).
- Length of PVC rule: 15cm.

> Biocompatibility

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: No sensitizing.
- ISO 10993-10: Negative intracutaneous irritation test.
- *Conclusion: product is biocompatible.*

> Sterilization and expiry date

- Sterile by gamma radiation.
- Expiry date: 3 years upon manufacturing date.

> Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature range: < 40°C
- Single use product. No maintenance required.

> Packaging

#	Ref	Packaging
TCH02	RQ-01 TO	Individual pouch with rule. Sterile product. Service Box 100 units.
TCH05	RQ-05 TO	Individual pouch with rule. Sterile product. Service Box 100 units.

> Instructions for use

- Clean and dry the patient's skin (Do not use the skin marker neither the ruler on wet skin).
- Mark the skin.
- Use iodide to disinfect the skin and go over the marking.
- Use 75% alcohol to disinfect the skin and perform the procedure.
- Remove the skin marking from the skin with alcohol, if needed.

Date: December 2023

Specification Nº: ETP/366/01

> Regulatory information

TELIC, S.A.U. guarantees that this product is in conformity with **Directive 93/42/EEC** and that it has been manufactured following the directives of the Quality Assurance System certified as **ISO 13485**.

This product is classified as:

- **Class I Sterile** product according to Annex IX of Directive 93/42/EEC, rule 1. (Reference RQ-01 y RQ-05)
- EMDN code: (V9004) Skin Markers.