

TWEEZERS

(EU) 2017/745 Annex XI-Part A Production Quality Assurance

Product Description	A hand-held manual instrument designed for non-specific gripping of devices, sponges and/or dressings during a procedure is disposable.
Product Class	(EU) 2017/745 Medical Device Regulation – Class Business Rule I
Manufacturer's Location	Tio Medikal 2/20 Sokak No:53 (Begos 3.Kuzey Giriş), 35400 Buca OSB / Buca / İzmir
Purpose of Usage	Tweezers are used in medical procedures to grasp, hold, or extract small tissues, foreign bodies, or surgical materials with precision. They help maintain a sterile field by minimizing direct contact, thus reducing the risk of infection and improving surgical accuracy.

Quality

- Manufactured under ISO 13485:2016 quality management standards.
- It has CE.

Bio-Compatibility

- Sterilized with ethylene oxide.

Related Standard

- ISO 13485:2016 Medical Devices Quality Management System
- 9001:2015 Quality Management System
- TS EN ISO 11607-1:2017 Packing for finally sterilised medical devices – Part 1: Rules for materials, sterile barrier system and packing systems / Products are made in accordance with the relevant standard.

Shelf Life

- 3 years

• Tweezers Image

• Tweezers Dimensions

A

A

	DIMENSIONS(CM)
REF CODES	A
640.01.002.01	15

Tolerances: ±3% (All sizes are produced & customisation)

Available Materials:
Polyamide Tıslamıd 6gf (COLOR PIGMENT %2)

Instruction for Use

- The package of products shall be opened in sterile and aseptical conditions.
- For a clean peel, open the package from the direction of the arrow slowly.
- There are labels or marks on the covers, which helps the user to follow patient direction and unfolding directions.

Do not use if package is damaged	Manufacturer	Sterilized using ethyleneoxide and single sterile barrier system	Use by date
Do not expose the product to sunlight.	Manufacturing date	Caution	Temperature limitation
Keep dry	Catalogue number	Unique device identifier	Consult instructions for use
Do not re-sterilize	Batch code	Medical device	
Single use (do not re-use)			