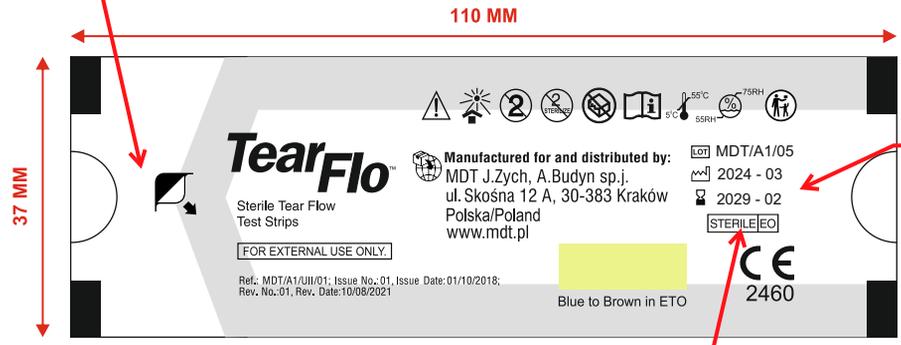


-su numatyta pakuotės atidarymo vieta.



-ant pakuotės pažymėtas produkto galiojimo laikas mėnesiais;

Note :
Indicator : 6mm x 17mm
Seal Zone : 7mm
Registration Mark : 4mm x 7.5mm
COLOR USE JET BLACK

-sterilios (simbolis ant pakuotės);



NEUROVITA ©

-baltas filtrinis, graduotas, milimetrinis popierius;

-su 35 įverčių graduote;

EN

TearFlo™ Sterile Tear Flow Test Strips (Schirmer Test)

Instructions for use

1. Intended use Intended for use during a tear secretion test. The Schirmer test is the oldest method of diagnosis of the dry eye syndrome (DES). **2. Product description** The TearFlo™ strip has a rounded, blunt end that should be placed under the lower eyelid without touching the cornea. The printed scale (0-35 mm), graduated in 1mm increments (± 0.03), has the accuracy of ± 1 mm. Each strip is individually packaged in a sealed and uncoated medical package and in film to ensure product sterility. **3. Indications** As recommended by the ophthalmologist. **4. Contraindications** Do not use in patients with damaged eye surface, inflammation, corneal or conjunctival ulceration, and in case of hypersensitivity to any of the product components. **5. Users** The product is designed exclusively for professional users. **6. Medical device class** An Im class medical device bearing the CE mark and having an EU declaration of conformity. **7. Use** Do not apply any topical medication or perform any manipulation on the eye prior to performing the examination. The examination room lighting should be dimmed. Position the patient in the examination chair with the head resting against the headrest. Be careful not to touch the rounded end of the strip when opening the package. With the patient looking up, carefully insert the rounded end under the lower part of the eye lid (about 10mm from the temporal edge or corner of the eye) and then bend the strip down slightly. Wait 5 minutes, remove the strip, and record the length of the moistened area, measuring from the folded part. Interpretation of results: >15 mm - normal result; 10-15 mm - indicates an initial deficit, and 5-10 mm - an increased deficit, of the aqueous component of tears; <5 mm - advanced DES. **8. Disposal** Because of the possibility of contamination, dispose of only with medical waste. The product is not recyclable.

Certificate of Analysis

Name of the product		SCHIRMER TEAR TEST STRIPS	
Certificate of Analysis Report No		MIPL/COA/A1/119	
Batch No.	MDT/A1/05 (MIPL/A1/119)	Batch Size	218587
Mfg. Date	2024-03	Exp. Date	2029-02

S.No	Parameters	Specifications	Observation	Mode of inspection	Reference
1	Visual	Free from burrs, foreign material	Complies	Visual Inspection	MIPL/SPC/FG/A1/01
2	Width of Strip	5.0 ± 0.50 mm	5.00	Vernier caliper	MIPL/DRG/A1/01
3	Total Length of Strip	41.00 ± 0.50 mm	40.98	Vernier caliper	
4	Distance of Marking from tip	5.0 ± 0.50 mm	5.02	Vernier caliper	
5	Thickness of Strip	0.22 ± 0.02mm	0.216	Micrometer	
6	Shape of Tip	Round	Complies	Visual Inspection	
7	Surface and Cutting of Strip	Shall be smooth and free from buckle edge, burr	Complies	Visual Inspection	MIPL/SPC/FG/A1/01
8	Quantity of Schirmer Tear Test Strip per primary packing pouch	One pc. per pouch	Complies	Visual by counting	EN ISO 868-5:2018
9	Integrity of primary packing pouch	Shall have no Leakage	Complies	Vacuum Desiccator	
10	Strength of seal joint in primary packing pouch	Shall be ≥1.2 N/15mm	7.65	Pull push meter	
11	Peel open characteristic	Seal shall be OK and extend along the total width and length of seal lines	Complies	Visual	MIPL/SPC/FG/A1/01
12	Printing matter on primary packing pouch	As per approved design	Complies	Visual	
13.	Quantity of Schirmer Tear Test Strip pouches in secondary box	100/50 pouches per secondary box as per approved artwork	Complies	Visual by counting	

Vernier matavimai: ilgis: 4,098 cm;

Certificate of Analysis

14	Integrity of secondary packing box	No damage, good finish	Complies	Visual	
15	Printing of secondary packing box	As per approved design	Complies	Visual	
16	Label & stamping on secondary packing box	As per approved design	Complies	Visual	
17	Sterility	Must comply	Complies	External Lab Test Report No. CEM00732403	As per USP

Remarks:

The above Batch Comply/~~do not comply~~ as per ISO, USP & In-house Specifications.


11/04/2024
Prepared By
(Sign&Date)

Mohit
11-04-2024
Verified By
(Sign&Date)