

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN



MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GA6663225-208021**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

23/07/2025 - 22/07/2030

Sijil ini adalah dengan ini diberi kepada: **RAINBOW OCULAR DEVICES SDN BHD**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

**78A, JALAN BP7/8 BANDAR BUKIT PUCHONG,
47120 PUCHONG, SELANGOR,
47120 PUCHONG
SELANGOR DARUL EHSAN**

Peranan establismen
Role of establishment

Wakil Diberi Kuasa
Authorized Representative

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.

to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.

This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.



MURALITHARAN PARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
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This certificate is hereby issued to:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **Schirmer Tear Test Strips**
Medical Device Name

Kelas **CLASS A**
Class

Jenama
Brand

Tear Touch,

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **MADHU INSTRUMENTS PVT. LTD.**
Name and address of manufacturer **F-90/3D, OKHIA INDUSTRIAL AREA PHASE-1, NEW DELHI-110020 INDIA**
110020, INDIA

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Tear Touch	MIPL/A1	Schirmer Tear Test Strips
2	Tear Touch Blue	MIPL/A6	Tear strips with blue mark
"End Of Product List"			

DIAGNOSTIC STRIPS

Tear Touch

Schirmer Tear Test Strips

This diagnostic strip made from the Whatman Filter Paper No. 41 measures the amount of tear production.



Product Code	Description	Qty. per box
MIPL/A1	Schirmer Tear Test Strips	100 strips (Sterile)



Indications

- Used for measurement of tear production

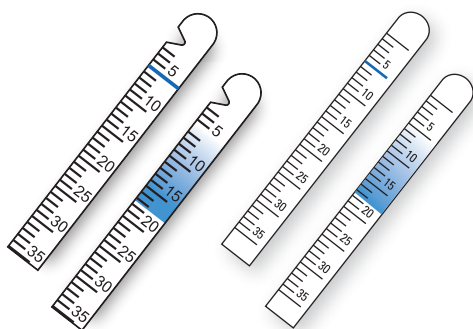
Specifications

- Each strip has a printed mm scale so that they can be easily read and recorded
- Available as sterile strips in individual pouches
- Innovative peel open packing pouch with transparent film on one side
- CE certified

Tear Touch Blu

Schirmer Tear Test Strips with Blue Mark

This diagnostic strip with Indicator Dye made from the Whatman Filter Paper No. 41 measures the amount of tear production.



Product Code	Description	Qty. per box
MIPL/A6	Schirmer Tear Test Strips with Blue Mark	100 strips (Sterile)
MIPL/A6/NT	Schirmer Tear Test Strips with Blue Mark (Notch)	100 strips (Sterile)



Indications

- Used for measurement of tear production

Specifications

- Each strip has a printed mm scale with Indicator Dye
- Can be kept for result comparison before and after treatment
- Innovative peel open packing pouch with transparent film on one side
- CE certified

[Tear Touch Schirmer strips MIPL/A1\(Box of 100 Strips\)](#)

Tear Touch Schirmer Strips are sterile diagnostic tools used by eye care professionals to measure tear production, primarily to diagnose [dry eye syndrome](#). These strips are made from high-quality Whatman No. 41 filter paper and feature a printed millimetre scale for precise reading.

Key Features

- **Sterility & Packaging:** Each strip is individually sealed in a [sterile pouch](#) with a transparent film on one side for quick visual inspection before use.
- **Measurement Aid:** Some versions, like **Tear Touch Blu**, include a distinct blue mark that moves with the moisture, making the tear level easier to read against the calibrated scale.
- **Patient Comfort:** The strips are designed with smooth, rounded tips and high-quality paper reported to cause less reflex tearing and irritation than standard filter paper.

The Schirmer Test Procedure

The test typically takes five minutes and involves the following steps:

1. **Preparation:** The examiner may use numbing drops to measure "basal" tear production or perform it without drops to measure "total" (including reflex) tearing.
2. **Placement:** The folded end of the strip is gently placed in the [lower eyelid](#) (inferior fornix), usually at the junction of the middle and outer thirds.
3. **Wetting:** The patient keeps their eyes gently closed for five minutes while the strip absorbs tears via [capillary action](#).
4. **Measurement:** The strip is removed, and the length of the wetted area is measured in millimetres.

Interpreting Results

Results can vary by age and whether anaesthesia was used, but generally:

- **Normal:** Wetting of **15 mm or more** in 5 minutes.
- **Mild to Moderate Dry Eye:** Wetting between **5 mm and 14 mm**.
- **Severe Dry Eye:** Wetting of **less than 5 mm**.

Tear Touch BLUE Schirmer strips MIPL/A1(Box of 100 Strips)

Schirmer strips are sterile, diagnostic tools used by eye care professionals to measure tear production, primarily for diagnosing dry eye syndrome. These strips are made from specialized filter paper and feature a distinctive **blue indicator dye** that makes it easier to see and record the moistened length after a test.

Key Features and Specifications

- **Measurement Precision:** Each strip is precision-engineered for a 1.0 mg measurement and includes a printed millimetre (mm) scale from 0 to 35 mm.
- **Indicator Dye:** The "Blu" variant specifically uses a blue mark or band to **enhance visibility, allowing for quick, accurate readings by clinical assistants.**
- **Material:** Made from medical-grade cellulose fiber, specifically Whatman No. 41 filter paper.
- **Packaging:** Available in packs of 100 or 200, with strips individually sealed in transparent, easy-peel pouches to maintain sterility.

Test Procedure and Interpretation

A qualified medical practitioner typically performs the Schirmer test over exactly **5 minutes**.

1. **Placement:** The rounded, folded end of the strip is inserted into the lower temporal lid margin while the patient looks up.
2. **Duration:** The patient closes their eyes gently for 5 minutes as the paper absorbs tears via capillary action.
3. **Measurement:** The strip is removed, and the length of the moistened area—indicated by the blue dye—is recorded in millimetres.

Common Results Interpretation (without anesthesia):

- **Normal:** > 15 mm of wetting.
- **Borderline/Mild Dry Eye:** 10–15 mm.
- **Moderate Dry Eye:** 5–10 mm.
- **Severe Dry Eye:** 0–5 mm.



Dated 16th April 2026

RAINBOW OCULAR DEVICES SDN BHD
Company Reg No: 202401048133 (1593978-A)

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