

**Technical Construction File
(TE/TCF/03)**

Issue No.: 01
Dated :01/10/2014
Rev.No.:00



TARUN ENTERPRISES

8/8, Strachy Road, Allahabad- 211001,U.P., India
info@optitecheyecare.com

**Product Information for Ophthalmic
Fluorescein Sodium Strips U.S.P.**

Section No.: 19-F
Page 1 of 2

Product- Ophthalmic Fluorescein Sodium Strips U.S.P.

1. Intended use:

Fluorescein Sodium Strips are intended to be used for evaluating contact lens fitting. This is used for staining the anterior segment of the eye for suspected corneal injury, and in applanation tomometry.

Classification: The device is non invasive and for transit use less than 5 seconds and supplied in sterile condition. As per Annex IX, Rule 5 of directive MDD 93/42 EC. The device is in Class Is.

2. Device description

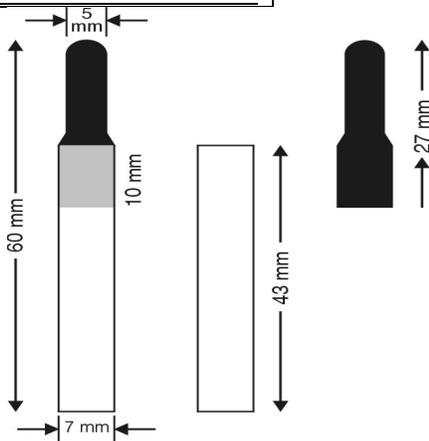
A disposable Whatman filter paper No 1 round blunt tip (impregnated with Fluorescein Sodium dye) sandwiched between a sticker paper stick (overall length 60mm). Each strip is packed individually in pouches before sterilization.

Ophthalmic Diagnostic Fluorescein Strips. These are made of whatman filter paper no. 1, with an overall size of 60mm, the tip which measures 27, mm is covered by dye.

3. Photographs-



170 p. Testų juotelės skirtos akies ragenos epitelio pralaidumo diagnostikai. Parodo gleivių sluoksnio kokybę, skirtas ragenos pažeidimams diagnozuoti, priekiniam akies segmentui dažyti. Kiekviena juostelė impregnuota mažo molekulinio svorio natrio fluoresceinu, įpakauta individualiame steriliame įpakavime. Rezultatai gaunami per 5 sek.

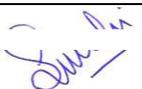
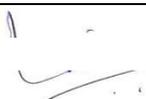


Prepared & Issued By: MR		Checked & Approved By: CEO	
		ggi	

Technical Construction File (TE/TCF/03)	Issue No.: 01 Dated :01/10/2014 Rev.No.:00	 TARUN ENTERPRISES 8/8, Strachy Road, Allahabad- 211001,U.P., India info@optitecheyecare.com
Product Information for Ophthalmic Fluorescein Sodium Strips U.S.P.	Section No.: 19-F Page 2 of 2	

4. Product standards- In house (Refer quality plan and technical specification section 22-F)

5. Shelf Life: Based on stability studies, the product's life is recommended to 5 years from the date of manufacturing. The product life is mentioned on the product label.

Prepared & Issued By: MR		Checked & Approved By: CEO	
Suruchi Batra		Tarun Jaggi	

**Technical Construction File
(TE/TCF/03)**

Issue No.: 01
Dated :01/10/2014
Rev.No.:00



TARUN ENTERPRISES

8/8, Strachy Road, Allahabad- 211001,U.P., India
info@optitecheyecare.com

**Product Information for Ophthalmic
Diagnostic Strips**

Section No.: 19-D
Page 1 of 2

Product- Ophthalmic Diagnostic Strips

1. Intended use:

Ophthalmic Diagnostic Schirmer Strips.

1. Assessment of normal tear production.
2. Chronic mucoid epiphora
3. Chronic pigmentary Keratitis
4. Epiphora

171 p. Kiekviena juostelė individualime steriliame įpakavime.

The prepackaged, sterile strips are removed and rounded end is placed in the lower conjunctival fornix, do not touch this end. The eye is closed for 1minute. Strip is then removed, and with a standard measurement chart is measured and recorded.

171 p. Rezultatai gaunami per 1 min.

Ophthalmic Diagnostic Schirmer Mark Blu Strips.

This is used in Ophthalmology for measurement of tears during surgery and flow of tears is detected by color for best visibility & accuracy.

171 p. Skirtos sausų akių sindromo diagnostikai iš ašarų.

Classification:

The device covered under Class Is as per Rule 5 Annex IX. This is ETO sterile and is for single use.

2. Device description

Ophthalmic Diagnostic Schirmer Strips.

This is used to measure the tear count in the eye; this is disposable, use and throw product. The device is sterilized and made of what man paper Grade NO. 41. The length of the strip is 42mm and the width is 5mm with a round end at the top, and graduations on the strips to measure the tear flow.

Ophthalmic Diagnostic Schirmer Mark Blu Strips.

Diagnostic Ophthalmic Sterile Strips, individually wrapped, and gauged for easy reading, helps measure the amount of tear production.

Normal	25mm- 30mm
Dry Eyes	11mm- 15mm
Mild Dryness	06mm- 10mm
Moderate Dryness	02mm- 05mm
Severe Dryness	00mm- 01mm

15mm is taken within normal limits.

Prepared & Issued By: MR			
Suruchi Batra		Tarun Jaggi	

**Technical Construction File
(TE/TCF/03)**

Issue No.: 01
Dated :01/10/2014
Rev.No.:00



TARUN ENTERPRISES

8/8, Strachy Road, Allahabad- 211001,U.P., India
info@optitecheyecare.com

**Product Information for Ophthalmic
Diagnostic Strips**

Section No.: 19-D
Page 2 of 2

3. Photographs- Ophthalmic Diagnostic Strips

SCHIRMER TEAR TEST STRIPS	MARK BLU SCHIRMER TEAR TEST STRIPS



171 p. Juostelių gradacija nuo 0-35 mm.

Schirmer Tear Test



Read the clear blue indicator

Mark Blu Schirmer Tear Test Strips

Note: For drawing details of Schirmer Tear Test Strips refer TE/DRG/STT
Mark Blu Schirmer Tear Test Strips refer TE/DRG/MBS

4. Product standards- In house (Refer quality plan and technical specification section 22-D)

5. Shelf Life: Based on stability studies, the product's life is recommended to 5 years from the date of manufacturing. The product life is mentioned on the product label.

Prepared & Issued By: MR		Checked & Approved By: CEO	
Suruchi			

With more than 30 million bottles sold all over the world, SuperOttik Anti-Reflex Lens Cleaner is not only the best anti-fog detergent - completely alcohol-free - for cleaning anti-reflective, polarized and transition lenses as well as traditional ones, but it is also the No. 1 in sales, and this is why it is used by all the major international optical companies.

Thanks to its secret herbal formula, completely natural and completely alcohol-free, it is the only product capable of perfectly cleaning any type of spectacle lens, be it prescription or sunglasses, keeping it transparent for several days thanks to a very thin film that it releases on the surface of the lenses after each cleaning. This film not only protects the lenses, but also manages to avoid the annoyance of their fogging.

But the greatest advantage, which makes SuperOttik Anti-Reflex Lens Cleaner a unique product, unlike all the alcohol-based ones on the market, is its ability to not damage the surface of the lenses in any way, particularly those that have undergone treatment that made them anti-reflective, polarized or transition.

191 p. Skystis nuo optikos rasojimo SuperOttik 33 ml.

