

# APPAVISC PFS

## Hydroxypropyl Methyl Cellulose Ophthalmic Solution USP

### PRODUCT DESCRIPTION

Appavisc is a viscoelastic solution of optimum viscosity. It contains highly purified grade of HPMC 2% w/v. It is clear isotonic sterile, non-inflammatory, used as a lubricant and protector in IOL surgery.

### COMPOSITION

Each mL contains:

Hydroxy Propyl Methyl Cellulose USP ...2%w/v  
Sterile Isotonic base q.s.

#### → Product Features

- Clear Visualization
- Preservative free sterile solution
- Optimum Viscosity
- Better chamber maintenance
- Friendly with corneal endothelium
- Provide excellent Lubrication
- Simple to remove from the anterior chamber

#### → Packaging

**Primary Packing:-** 2 & 3 ml plastic syringes, plunger stopper, plunger rod & pouch

**Secondary Packing:-** Carton box with 23G Sterile Cannula .

#### → Shelf Life

24 months from the date of manufacturing.

#### → Storage:

Store between 15°C-25°C



#### USES:

Appavisc 2%w/v injection is used to relieve burning, irritation and discomfort of dry eye conditions associated with deficient tear production, infrequent blinking, smoke, wind, pollution, extended use of computer screen or television, medical treatment, dry atmospheric conditions (air-conditioning, central heating). It may also be used to aid insertion of hard contact lenses and increase comfort during wear. It is also indicated to aid certain eye examinations and surgeries.

#### HOW IT WORKS:

Appavisc 2%w/v injection belongs to a class of medicines called eye lubricants or artificial tears. It reduces dryness and irritation by wetting and lubricating the surface of eye.

**SUPPLY:** Available in 2ml and 3ml Sterile pre-filled syringes. one HDPE syringe packed with pouch printed labelled & carton and carton packed in corrugated box

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- Clear Visualization
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- Optimum Viscosity
- Better chamber maintenance
- Friendly with corneal endothelium
- Provide excellent Lubrication
- Simple to remove from the anterior chamber

### → Packaging:

**Primary Packing** - 5ml Glass vials, rubber stopper, aluminium seal & pouch

**Secondary Packing** - Carton box with 23G Sterile Cannula.

### → Shelf Life:

24 months

### → Storage:

Store between 15°C-25°C



**INDICATIONS:** Appavisc is indicated as a surgical aid (medical device) during surgical procedures involving the anterior chamber of the eye, including extraction of the lens and insertion of intraocular lenses. It maintains the depth of the anterior chamber during the whole surgical procedure and permits greater operative precision without the risk of damaging the endothelium of the cornea or other intraocular tissues.

**DOSAGE AND ADMINISTRATION:** APPAVISC (Hydroxypropyl Methyl Cellulose Ophthalmic Solution USP) should be carefully introduced into the anterior chamber using the sterile cannula. It may be applied into the chamber prior to or following delivery of intraocular lens (IOL). It may be used to coat an intraocular lens as well as tips of surgical instruments prior to implantation which protect the corneal endothelium from possible damage during cataract surgical procedure.

### SUPPLY: APPAVISC

(Hydroxypropyl Methylcellulose Ophthalmic Solution USP) is a sterile, non-pyrogenic, viscoelastic preparation supplied in 5mL glass Vials with single use sterile cannula.

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:  
10000402971-PA-NA-IND Rev.0.0

Project No.:  
PRJN-197028-2020-PA-IND

Initial Certification Date: 17 February 2021  
Valid Until: 16 February 2024

This is to certify that the management system of:

## Appasamy Ocular Devices (P) Ltd

R.S. No. 9/1, 2 & 3, NH-45A, Villupuram Main Road, Vadamangalam,  
Puducherry, 605102, INDIA

Complies with the requirements of:

**ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**Design and Development, Manufacture and Sale of Sterile  
Ophthalmic Solutions.**

Place and date:  
Høvik, 17 February 2021

For:  
DNV GL PRESAFE AS



*Eugenie Winger Husebye*  
Eugenie Winger Husebye

The certificate is digitally verified by blockchain  
technology. For more info, see  
[www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.: 10000402970-PA-NA-IND Rev 0.0

Project No.: PRJN-197028-2020-PA-IND

Valid Until: 26 May 2024

This is to certify that the quality system of:

### **Appasamy Ocular Devices (P) Ltd**

R.S. No. 9/1,2 & 3, NH-45A, Villupuram Main Road, Vadamangalam,  
Puducherry - 605 102, India

For design, production and final product inspection/testing of:

### **STERILE OPHTHALMIC SOLUTIONS**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II  
excluding section 4 of Council Directive 93/42/EEC on Medical  
Devices, as amended**

and found to comply

Place and date:  
**Høvik, 26 April 2021**

Check Validity

For the issuing office:  
**Notified Body 2460  
DNV Product Assurance AS**



*Eugenie Winger Husebye*  
**Eugenie Winger Husebye**  
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-11-MDD-f2, rev.0

Further details of the product(s) and conditions for certification are given overleaf.

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

## Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	26 April 2021

## Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Ophthalmic Solutions	1.Ophthalmic Viscosurgical Device - Hydroxypropyl methyl cellulose sterile ophthalmic solution(E4M) USP 2% w/v Brand: APPAVISC Size:3ml,5ml – Vials Brand: APPAVISC PFS Size:2ml,3ml - PFS	IIb
	2.Ophthalmic Viscosurgical Device - Hydroxypropyl methyl cellulose sterile ophthalmic solution (E10M) USP 2% w/v Brand: APPAVISC HVPFS Size:2ml - PFS	
	3. Ophthalmic Viscosurgical Device- Sodium Hyaluronate Sterile Ophthalmic Solution 10 mg Brand : Cohevisc 1.0 Size: 1ml in 2.25ml Glass Syringe 4.Ophthalmic Viscosurgical Device- Sodium Hyaluronate Sterile Ophthalmic Solution 14 mg Brand: Cohevisc 1.4 Size: 1ml in 2.25ml Glass Syringe	IIb
	5. Trypan blue solution 0.8 mg Brand: Rhex-ID Size: 1ml,2ml-vials	IIb

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-i1-MDD-f2, rev.0



The complete list of devices is filed with the Notified Body

#### Sites covered by this certificate

Site Name	Address
Appasamy Ocular Devices (P) Ltd.	R.S. No. 9/1, 2 & 3, NH-45A, Villupuram Main Road, Vadamangalam, Puducherry - 605 102, India

#### EU Representative

Emergo Europe B.V, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands

#### Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

#### Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate