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EC CERTIFICATE
Full Quality Assurance System

Certificate No.:
10000322044-PA-NA-IND

Project No.:
PRJC-599999-2019-MSC-IND

Valid Until:
26 May 2024

This is to certify that the quality system of:

APPASAMY OCULAR DEVICES (P) Ltd.

Plot No.74-D, Katha, BADDI, Distt Solan,Himachal Pradesh - 173 205, 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

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

Place and date:
Høvik, 10 May 2021

Check Validity

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

Hazem Tinawi
Technical Reviewer

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	10 May 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Ophthalmic Viscosurgical Solution	1.Ophthalmic Viscosurgical Device - Hydroxypropyl methyl cellulose sterile ophthalmic solution(E_4M) USP 2% w/v Brand: APPAVISC Size:3ml,5ml – Vials Brand: APPAVISC PFS Size:2ml,3ml - PFS 2.Ophthalmic Viscosurgical Device - Hydroxypropyl methyl cellulose sterile ophthalmic solution (E_{10}M) USP 2% w/v Brand: APPAVISC HVPFS Size: 2ml - PFS	IIb
Ophthalmic Viscosurgical Solution	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 5. Ophthalmic Viscosurgical Device- Sodium Hyaluronate Sterile Ophthalmic Solution 18 mg Brand: Cohevisc 1.8	IIb

	Size: 1ml in 2.25ml Glass Syringe	
Ophthalmic Surgical Solution	6. Trypan blue solution 0.6 mg Brand: Trypan blue solution Size: 1ml,2ml-vials 7. Trypan blue solution 0.8 mg Brand: Rhex-ID Size: 1ml,2ml-vials	IIb
Ophthalmic Surgical Solution	CLEARSOL Size:100 ml,250 ml and 500 ml	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
APPASAMY OCULAR DEVICES (P) Ltd.	Plot No.74-D, Katha, BADDI, Distt Solan,Himachal Pradesh - 173 205, India

EU Representative

Amstermed B. V., Van der Burchstraat 28, 2132 RN Hoofddorp, 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