EC CERTIFICATE

Full Quality Assurance System

Certificate No.:10000359965-PA-NA-IND Rev. 0.0 Project No.: PRJC-525190-2015-PRC-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 45 – A, Villupuram Main Road, Vadamangalam,
Puducherry – 605102, India

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

STERILE FOLDABLE OPHTHALMIC INTRA OCULAR LENS-MULTI FOCAL & TORIC

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, 4 May 2021

Digitally signed by Perminov Andrei
Date: 2022.02.04 15:22:39 EET
Reason: MoldSign Signature
Location: Moldova

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

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.

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	4 May 2021

Products covered by this Certificate:

Product Description	Product Name		Class
Sterile Ophthalmic Intra Ocular Lens-Foldable Hydrophobic	SUPRAPHOB REGEN	SP MFDY 200	Class IIb
	SUPRAPHOB TORIC	SP TORIC, T3-T9	
	SUPRAPHOB INFOCUS	SP INFO	

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 45 – A, Villupuram Main Road, Vadamangalam, Puducherry – 605102

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