EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 11657-2017-CE-IND-NA-PS Rev. 2.0 Project No.: PRJC-525190-2015-PRC-IND Valid Until: 27 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 OPHTHALMIC INTRA OCULAR LENS, STERILE FOLDABLE OPHTHALMIC INTRA OCULAR LENS & STERILE INJECTOR DELIVERY SYSTEM

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, 23 April 2021

Check Validity

Digitally signed by Perminov Andrei
Date: 2022.02.04 15:22:32 EET
Reason: MoldSign Signature
Location: Moldova

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

Eugenie Winger Husebye
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	07-01-2016
0.0	Supersedes DNV GL (NB 0434) certificate No. 7116-2015-CE-IND-NA Rev 1.0 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	22-11-2017
1.0	Addition of new devices (in bold)	07-08-2018
2.0	**Recertification**	**23-04-2021**

Products covered by this Certificate:

Product Description	Product Name		Class
Sterile Ophthalmic Intra Ocular Lens-PMMA	Appa Lens	100, 102, 105, 107, 108, 109 & 110	IIb
	Appa Lens Plus	SQ100 & SQ102	
	Liberty Lens	100L, 102L, 105L, 107L & 109L	
	Liberty Lens Plus	MF207	
	Heera Lens	100H, 105H, 107H, 108H & 109H	
	Swiss Lens	SQ50120, SQ55120 & SQ55125	
	Appa Lens	101	
	Appa Lens Plus	SQ101	
	Liberty Lens	101L	

	Heera Lens: 101H Swiss Lens: SQ52120 Appa Lens: 205, 206, 208, 209 & 210 Appa Lens Plus: SQ205 & SQ209 Liberty Lens: 205L, 206L, 208L, 209L, 210L & 220L Heera Lens: 205H, 206H, 208H & 209H Swiss Lens: SQ60130 & SQ65130 Appa Lens: 207 Appa Lens Plus: SQ207 Liberty Lens: 207L Heera Lens: 207H Swiss Lens: SQ60125 Swiss Lens HD: SHD701 Appa Lens: 302 Liberty Lens: 302L Heera Lens: 302H Liberty Lens: 407L Liberty Lens: 303L	
Sterile Ophthalmic Intra Ocular Lens-Foldable Hydrophilic	Acryfold: 502 Ezyfold: 502 Swiss Fold: SFC6 Acryfold: 601 Centry fold: 601 Naspro: NAS207 & NAST207 Swiss Fold-HD: SFAC6 Acryfold: 701 Acryfold: ULTRASMART	Class IIb

	MULTIDIFF	MFD605, MFDY605	
	Acryfold BBY	BB602	
	Naspro BBY	NASY 207	
Sterile Ophthalmic Intra Ocular Lens-Foldable Hydrophobic	Supraphob	SPNT 200, HPNT 200 & HPNT 300	Class IIb
		SPNT 300	
	Supraphob BBY	SPNT 200-PL & Supraphob BBY	
	Maxim IOL	Supraphob BBY	
	Supraphob BBY	SPNT 300-PL	
	Swiss phob	SPH 60130	
Sterile Injector Delivery System	Pinnacle	SP-01,AE-01, GF-01,GF-02, GF-03,GF-01A, GF-03A,DIS-2.8, DIS-2.2,DIS-1.8, DIS-2.0,DIS-2.4, DPIS-2.8 & DPIS-2.2, DPIS-2.4	Class 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.,	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