

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 287297-2019-CE-IND-NA-PS Rev 1 Project No.: PRJC-534183-2015-MSL-IND Valid Until: 28 April 2024

This is to certify that the quality system of:

Caregroup Sight Solution Private Limited

Block No. 310/C&E, Village Dabhasa, Taluka - Padra, Dist. Vadodara-391440, Gujarat, India

For design, production and final product inspection/testing of: Sterile Intraocular Lenses and Accessories & Devices for Intraocular Surgery

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, 11 August 2020



PROD 021

For: DNV GL PRESAFE AS Notified Body No.: 2460

DO

Palani Damodharan

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



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: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA.

DNV.GL

Certificate No.: 287297-2019-CE-IND-NA-PS Rev 1	Project No.:Valid Until:PRJC-534183-2015-MSL-IND28 April 2024
	 EPCLT142, EPCLT145, EPCLT147, EPCLT15, EPCLT152, EPCLT155, EPCLT157, EPCLST Trade name: IPCL Toric, IPCL V2.0 Toric IPCLT10, IPCLT105, IPCLT11, IPCLT112, IPCLT115, IPCLT117, IPCLT12, IPCLT122, IPCLT125, IPCLT127, IPCLT13, IPCLT132, IPCLT135, IPCLT136, IPCLT137, IPCLT14, IPCLT142, IPCLT145, IPCLT147, IPCLT15, IPCLT152, IPCLT155, IPCLT157, IPCLST
Hydrophobic Intraocular Lenses	 Clear /Yellow Hydrophobic Lenses (Square Edge, Aberration Free/controlled, Plus & Minus Power) Trade name: ACRIOL, ACRIOL EC, ACRIOL Pre- loaded AS-6, AS-7, AS-6CA, AS-6Y, AS-6HD Trade name: MAGNIFICENT UHDOF AS-6A, AS-6CA, AS-7 Trade name: Vista SPHERE VAB-6CL,VAB-6Y, Trade name: SpectraPhob SPH-6, SPH-6Y, Trade name: ACRIOL EC Versatile, ACRIOL EC Versatile Preloaded AS-6V, AS-6VP Trade name: EyeMax Mono AMDAS, AMDSP, AMDAS-2, AMDSP-2, AMDBAG, Eyemax PB, Eyemax B00, Trade name: TS Ibex TS60, Ibex TS70, Trade name: ARTIOLS ART-25, ART-40, ART-55, ART-70, Multifocal Hydrophobic Lenses (Clear/Yellow, Square Edge, Aberration Free/controlled) Trade name: ACRIOL MULTIFOCAL, AUTO-FOCUS AS-6M, AS-7 Hydrophobic Toric Lenses (Clear/Yellow, Square Edge, Multifocal/Diffractive-Refractive, Aberration Free/controlled - CYLINDER 0.5 TO 20.0 IN 0.5 STEP) Trade name: ACRIOL EC TORIC AS-6T, AS-6T1, AS-6T1.5, AS-6T2, AS-6T2, S, AS-6T3, AS-6T3, S-6T5, AS-6T4.5, AS-6T5, AS-6T3, AS-6T6.5, S, AS-6T7, AS-6T5, AS-6T8, AS-6T8.5, AS-6T6.5, AS-6T7, AS-6T5, AS-6T8, AS-6T8.5, AS-6T6.5, AS-6T7, AS-6T5, AS-6T8, AS-6T8.5, AS-6T9, AS-6T9.5, AS-6T10, AS-6UT, VAB-TR, AS-6AT Trade name: Acriol EC Versatile AS-6VT
	Diffractive- Refractive Lenses (Clear/Yellow,