Introduction

The Regulation (EU) 2017/745 on medical devices requires that the manufacturer shall draw up a summary of safety and clinical performance (SSCP) for implantable devices and for class III devices, other than custom-made or investigational devices. The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed).

The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device. The SSCP will be an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information.

The SSCP is not intended to:

- Give general advice on the diagnosis or treatment of particular medical conditions, nor
- Replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor
- Replace the mandatory information on implant cards or in any other mandatory documents.

The main purpose of this document is to provide guidance on the presentation, content and validation of the SSCP. The word "shall" is used when there is a corresponding "shall" in the MDR, otherwise "should" or "recommended" etc. is used indicating the interpretation of the MDR

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1 Device Brand / Trade Name(s)

Product Name:	Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded
Brand/Proprietary Name:	Galaxy Fold Superphob & Galaxy Fold Superphob Infocus.

1.2 Manufacturer's Name & Address

Name:	**Ellis Ophthalmic Technologies Inc.**
Address:	147-39, 175th Street, Suite #128, Jamaica, New York, USA.
Phone:	718-656-7390
Email:	sunilraja@eye-ellis.com
Website:	www.eye-ellis.com

1.3 Manufacturer's Single Registration Number (SRN)

US-MF-000014670

1.4 Basic UDI-DI

Sterile Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded-08466600SPHPHOBICGALAFSNL

1.5 Medical Device Nomenclature

EMDN Code: P030102090201 - IOLs, Aphakic, Monofocal, Aspheric, Hydrophobic Acrylic.
P030102100201 - IOLs, Aphakic, Multifocal, Aspheric, Hydrophobic Acrylic.

1.6 Class of device

Duration of Use	Long Term (>30 Days) / Continuous
Invasiveness	Surgically invasive device
Device Type	Non-active Medical Device & Implantable device
Rule Applicable	08
Classification	IIb
Reference	In accordance with Annex VIII of EU Medical Device Regulation 2017/745

1.7 Year of first certificate (CE) of the subject device

27/10/2017

1.8 Authorised Representative

Name:	**Amstermed B.V**
Address:	Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands.
Phone:	+31 23 5656337
Email:	info@amstermed.nl
Website:	www.amstermed.nl
SRN:	NL-AR-000001971

1.9 NB Details

Name:	**DNV Product Assurance AS**
Address:	Veritasveien 1, 1363 Høvik, Norway
Website:	www.dnv.com
Notified Body No.:	2460

1.10 Conformity Assessment Procedure

Conformity assessment procedure followed is Annexure IX.

2. Intended use of the device

2.1 Intended Purpose

IOL can be defined as 'Optical Implants for the replacement of the human crystalline lens in the visual correction of aphakia (cataract)'. Intraocular lens functions as a refracting medium to replace the natural lens in the correction of cataract.

2.2 Indications & Target Populations

- **Medical Indications**

  - Monocular Cataract
  - Mature Cataract
  - Congenital Cataract
  - Immature cataract
  - Refractive lens (Exchange) Relex
  - Traumatic Cataract
  - Binocular cataract

- **Target Population(s)**

Above age of one year (Male or Female)

2.3 Contraindications and/or Limitations

a. Superphob Infocus

- Chronic Severe Uveitis
- Epithelial Dystrophy
- Proliferative Diabetic Retinopathy
- Choroidal Hemorrhage
- Microphthalmos
- Concommitant Severe Eye Disease
- Rubella Cataract
- Massive Vitreous Loss
- Anirida
- Severe corneal dystrophy
- Glaucoma
- Non-age-related cataract
- Avoid implantation in eyes with fixed dilated pupil & miotic pupil
- Astigmatism

b. Superaphob

- Chronic Severe Uveitis
- Epithelial Dystrophy
- Proliferative Diabetic Retinopathy
- Choroidal Hemorrhage
- Microphthalmos
- Concommitant Severe Eye Disease
- Rubella Cataract
- Massive Vitreous Loss

- In Cataracts present in children
- Anirida
- Astigmatism

3. Device Description

3.1 Description of the Device

Foldable Intra Ocular Lens a medical device consisting of optic and haptic components, intended for surgical implantation inside the posterior chamber of the eye. IOL replaces the natural crystalline lens of the eye to rehabilitate the cataract patients. A Single Piece IOL is a device in which the haptic is continuous with the Phobic optic and fabricated from the same material.

3.1.1 Device Drawing

#	Variant Name	Image
1.	Galaxy Superphob (AE-01)	
2.	Galaxy Superphob Infocus (AE-INFO)	

3.1.2 Principle of Operation

Intraocular lenses work much in the same way as a natural lens would. As light rays enter the eye the IOL bends (or refracts) the light rays to help see with accuracy.

3.1.3 Mode of Operation

After proper examination and confirmed sterility, peel the blister and take the Semi-preloaded cartridge carefully. Close the cartridge and load into the injector. Apply HPMC Underneath the lens and also fill the tunnel of the cartridge front side. Gently push the piston forward, now the Lens is ready for implantation.

3.1.4 Design Characteristics

Galaxy Fold Superphob is a single piece hydrophobic acrylic lens manufactured from ultra-glistening free proprietary material with excellent compatibility.

- Glistening free -The material is free of microvacuoles and glistening. Glistening's are fluid filled microvacuoles that form within the matrix of the lens when exposed to aqueous environment. High levels of glistening result in scattering of light and reduced contrast sensitivity.
- Natural yellow - Proprietary natural yellow chromophore blocks harmful ultra-violet and blue light which cause
- Foldability and Memory - Handling characteristics and unfolding are optimal for placement inside the capsular bag.
- Aspheric surface - Negative spherical aberration design on anterior surface improves contrast sensitivity and low light visual acuity compared with spherical IOLs.
- Square Edge - 360-degree square edge design reduces the incidence of PCO and YAG capsulotomy rates.

- Stability - Dual muscle haptics design ensures perfect centration and stability inside the capsular bag.
- Ready to Use Semi-preloaded system.

3.1.5Method of Sterilization

Ethylene oxide gas sterilization

3.1.6Device Lifetime/Stability

The Life time of the Ophthalmic Foldable Intraocular Lens - Hydrophobic (Semi-Preloaded) is 15 Years after implantation

3.1.7Information about the constituents

a. Device with Medicinal Product

Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded does not incorporate medicinal substances. Hence this declaration is not applicable.

b. Device with Human or Animal Origin Tissues

Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded does not incorporate any human or animal origin tissues. Hence this declaration is not applicable.

c. Device with substances absorbed by or locally dispersed in the human body

O Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded does not incorporate any substances that absorbed by or locally dispersed in human body. Hence this declaration is not applicable.

d. Device with Carcinogenic, Mutagenic or Toxic to reproduction (CMR) or Endocrine-disrupting substances

Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded does not impact any Carcinogenic, Mutagenic or Toxic to reproduction (CMR). Hence this declaration is not applicable.

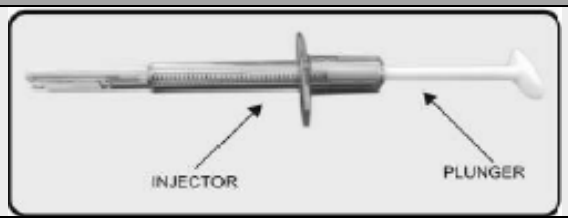
e. Materials could result sensitisation or an allergic reaction to patient/user

HEMA – Hydroxyethyl methacrylate

3.2 Reference to previous generation(s) or variants

Legacy Device Name:	Ophthalmic Foldable Intraocular Lens - Hydrophobic
Brand/Proprietary Name:	GALAXY FOLD
Models/Variants:	Superphob (AE-01), Superphob MF (AEM-01)
93/42/EEC (MDD) Cert. No.:	11330-2017-CE-IND-NA-PS
Notified Body Details:	DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway
Is any significant difference between Legacy Device & Device Under Evaluation?	There is no significant difference between legacy device and subject device with respect to raw materials used in production, device description, intended purpose, medical indications, target user, target patient population, side-effects, and contraindications.

3.3 Accessories Details

#	Accessory Name	Image	Material	Quantity
1.	Injector		Poly carbonate	01 o.

3.4 Combination with other Medical Devices

Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded is not used with any other medical device. Hence this declaration is not applicable.

4. Risks and warnings

4.1 Residual risks and undesirable side effects

Residual Risks

- Vision Loss, infection/allergic reaction, severe inflammation
- Toxic anterior segment syndrome, increased IOP, Haptic demolition or crack, Cloudy lens
- Wound Leakage, Corneal Edema, Blurred Vision, develop glare, halos, double vision, decreased vision

Potential Hazards

- Intra Ocular Foreign Body debris
- Temporary Corneal Edema
- Secondary Cataract Formation
- Malpositioned lens
- Aphakic Glaucoma
- Temporary Flat Anterior Chamber
- Retinal Detachment
- Posterior Capsule Opacification
- Cystic Macular Edema
- Iridocyclitis
- Iritis
- IOL dislocation and subluxation
- Lens implants loop amputation
- Endothelial Corneal Dystrophy
- Vitreous Herniation into the Anterior Chamber
- Infection
- Pupillary Block
- Corneal Dystrophy
- Hyalites
- Endophthalmia and Panophthalmia
- Recurrent anterior or posterior segment inflammation of unknown etiology
- IOL precipitates

4.2 Warnings

Intra Ocular Lens supplied is void of all warranties expressed or implied, if

- Do Not Resterilise. Resterilisation may compromise device performance, which could cause serious harm to the patient's health and safety.
- Do not store below 5°C and above 40°C to avoid shocks & fragile.
- Lens should not be altered in any manner.
- Lens should not be repackaged by anyone.
- Single use IOLs and single use injectors cannot be reused, as they are not designed to perform as intended after the first and only usage to avoid infection.
- Do not use after the expiry date.
- Non-toothed, polished instruments must be used if handling the IOL.
- Do not allow the IOL to contact substances that are unsterile or ocular-incompatible prior to placement into the eye.
- Do not use unsterile surgical instruments or instruments that may carry a risk of contamination.
- Do not allow the IOL to dehydrate during the procedure.
- Once closed, do not reopen the flaps of the injector.

- Following implantation, irrigate/aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule.

4.3 Other relevant aspects of safety

There were no identified and/or received reportable events that led to death, a serious deterioration in the state of health of the patient, user, or other person for Ophthalmic Foldable Intraocular Lens - Hydrophobic (Semi-Preloaded). Hence FSCA or FSN is not applicable.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device, if applicable

No equivalent device has been identified. The clinical evaluation of the Ophthalmic Foldable Hydrophobic Intraocular Lens_Semi Preloaded is based on the available clinical data collected for the device itself, including preclinical testing, bench performance data, and clinical experience. The safety and performance profile of the device has been assessed in accordance with relevant standards and guidelines, demonstrating that the device meets its intended purpose and performs as intended.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not Applicable

5.3 Summary of clinical data from other sources, if applicable

Literature evidence - Pertinent Literatures for Appraisal

#	ID#	Source Link	Literature Title
1.	L1	https://pubmed.ncbi.nlm.nih.gov/26100954/	Glistenings 9 years after phacoemulsification in hydrophobic and hydrophilic acrylic intraocular lenses
2.	L2	https://pubmed.ncbi.nlm.nih.gov/27521667/	Brown discoloration of acrylic hydrophobic intraocular lens
3.	L4	https://pubmed.ncbi.nlm.nih.gov/27445063/	Posterior capsule opacification 9 years after phacoemulsification with a hydrophobic and a hydrophilic intraocular lens
4.	L6	https://pubmed.ncbi.nlm.nih.gov/29934027/	Posterior capsule opacification, glistenings and visual outcomes: 3 years after implantation of a new hydrophobic IOL
5.	L7	https://pubmed.ncbi.nlm.nih.gov/31436185/	A comparison of posterior capsular opacification after implantation of three different hydrophobic square edge intraocular lenses
6.	L8	https://pubmed.ncbi.nlm.nih.gov/22727297/	Assessment of new-generation glistening-free hydrophobic acrylic intraocular lens material
7.	L9	https://pubmed.ncbi.nlm.nih.gov/26067189/	The effect of single-piece hydrophobic acrylic intraocular lenses on the development of posterior capsule opacification
8.	L10	https://pubmed.ncbi.nlm.nih.gov/20610089/	Three-year stability of an angle-supported foldable hydrophobic acrylic phakic intraocular lens evaluated by Scheimpflug photography
9.	L11	https://pubmed.ncbi.nlm.nih.gov/24223736/	Effect of hydrophobic acrylic versus hydrophilic acrylic intraocular lens on posterior capsule opacification: meta-analysis
10.	L12	https://pubmed.ncbi.nlm.nih.gov/28366371/	Intraindividual comparison of capsule behavior of 2 hydrophobic acrylic

#	ID#	Source Link	Literature Title
			intraocular lenses during a 5- year follow-up
11.	L13	https://pubmed.ncbi.nlm.nih.gov/38155684/	Extended depth of focus intraocular lens versus a new monofocal intraocular lens: A prospective comparative and interventional study
12.	L14	https://pubmed.ncbi.nlm.nih.gov/23471324/	Effect of aspherical and yellow tinted intraocular lens on blue-on-yellow perimetry
13.	L15	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3937253/	Clinical properties of a novel, glistening-free, single-piece, hydrophobic acrylic IOL
14.	L16	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4559235/	A pilot study to determine if intraocular lens choice at the time of cataract surgery has an impact on patient-reported driving habits
15.	L17	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3843900/	Patient-Reported Difference following Implantation of a Blue Light-Filtering Aspheric Intraocular Lens and a UV-Filtering Aspheric Intraocular Lens
16.	L18	https://www.semanticscholar.org/paper/Comparison-of-visual-function-with-aspheric-yellow%2C-K%C3%BCchle/e47e23545874ce1174b1821d88b415e4aeb141f8	Comparison of visual function with aspheric yellow, aspheric clear and spherical clear intraocular lenses
17.	L20	https://pubmed.ncbi.nlm.nih.gov/20665986/	Clinical study of Acrysof IQ aspheric intraocular lenses.
18.	L21	https://pubmed.ncbi.nlm.nih.gov/29736282/	Biomaterial Influence on Intraocular Lens Performance: An Overview
19.	L22	https://pubmed.ncbi.nlm.nih.gov/22287168/	Contrast sensitivity and color perception with orange and yellow intraocular lenses
20.	L24	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6188169/	Long-term effectiveness and safety of a three-piece acrylic hydrophobic intraocular lens modified with hydroxyethyl-methacrylate: an open-label, 3-year follow-up study
21.	L25	https://link.springer.com/chapter/10.1007/3-540-26678-X_4	Foldable Intraocular Lenses
22.	L26	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5142717/	Evaluating the Biostability of Yellow and Clear Intraocular Lenses with a System Simulating Natural Intraocular Environment
23.	L27	https://pubmed.ncbi.nlm.nih.gov/23677137/	Posterior Capsule Opacification with the iMics1 NY-60 and AcrySof SN60WF 1-Piece Hydrophobic Acrylic Intraocular Lenses: 3-Year Results of a Randomized Trial
24.	L28	https://pubmed.ncbi.nlm.nih.gov/31564314/	Blue light–filtering and violet light–filtering hydrophobic acrylic foldable intraocular lenses: Intraindividual comparison
25.	L29	https://pubmed.ncbi.nlm.nih.gov/24729678/	Safety and effectiveness of a single-piece hydrophobic acrylic intraocular lens (enVista®) – results of a European and Asian-Pacific study
26.	L30	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3614664/	Post-Operative Capsular Opacification: A Review

#	ID#	Source Link	Literature Title
27.	L32	https://pubmed.ncbi.nlm.nih.gov/22094397/	Measurements of transmission spectrums and estimation of retinal blue-light irradiance values of currently available clear and yellow-tinted intraocular lenses
28.	L33	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6432853/	A comparison of the contrast sensitivity function between age-matched phakic emmetropes and pseudophakic individuals with aspheric intraocular lenses
29.	L34	https://pubmed.ncbi.nlm.nih.gov/32971619/	Visual outcomes of binocular implantation of a new extended depth of focus intraocular lens
30.	L35	https://www.touchophthalmology.com/wp-content/uploads/sites/16/2015/07/davison.pdf	Achieving Best Visual Outcomes with a Monofocal Intraocular Lens

Refer Attachment 11 of CER (CER-SP-01) for the detailed literature summary and literature appraisal.

5.4 PMCF Clinical Safety & Performance data

A PMCF plan has been developed in accordance with Annex XIV, Part B of Regulation (EU) 2017/745 and MDCG 2020-7- Post-Market Clinical Follow-Up (PMCF) Plan A guide for manufacturers and notified bodies to collect and evaluate clinical data on the device's performance and safety. The PMCF activities include:

- Clinical data registry
- Screening of scientific literatures
- Real world evidences
- PMS Survey
- PMCF study

PMCF study Result:

I. Performance Evaluation

1. Visual Acuity

An intraocular lens implant is an artificial replacement for the lens of the eye. It's part of the surgery to fix cataracts. Hence to improve the vision patients usually undergo replacement of natural crystalline lens with intraocular lens (IOLs). Post-surgery usually within eight weeks, the eyes should have fully healed and vision should be stable. Visual acuity refers to the ability to distinguish the details of the object and shape at a given distance. Here, in order to understand the improvement in patient health condition, before surgery the visual acuity is measured and post-surgery re test is performed.

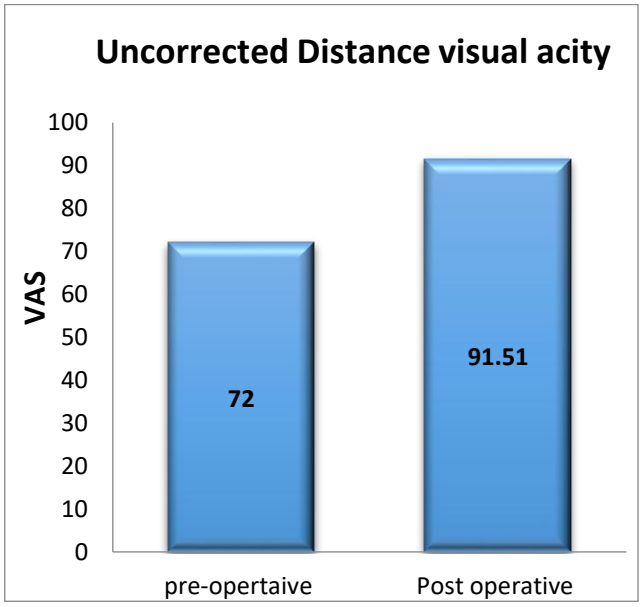
Measurement of Uncorrected distance Visual Acuity and Best distance corrected Visual Acuity is recorded. Uncorrected distance Visual Acuity is defined as visual acuity measured without correcting refractive errors, which is also known as UDVA and Best distance corrected Visual Acuity is examined after correcting refractive errors, which is also known as BDVA. LogMAR notation is widely used in scientific publications (i.e, logMAR scale is calculated as log (MAR) = log (1/V) = - log (V)). The value "0" indicates "no loss", that is visual acuity equal to the reference standard (1.0, 20/20). The VAS scale (VAS = Visual Acuity Score) serves the same purpose. Its formula is: 100 - 50 x log MAR. In all the entities like UDVA, BDVA post implantation of IOL there is an increment in the VAS value which shows improvement in the vision of the subjects.

Dr. Kumaran eye Hospital

Description for Visual Acuity in Vas in pre and post-operative Ophthalmic Foldable Intraocular Lens-Hydrophobic treatment is given below:

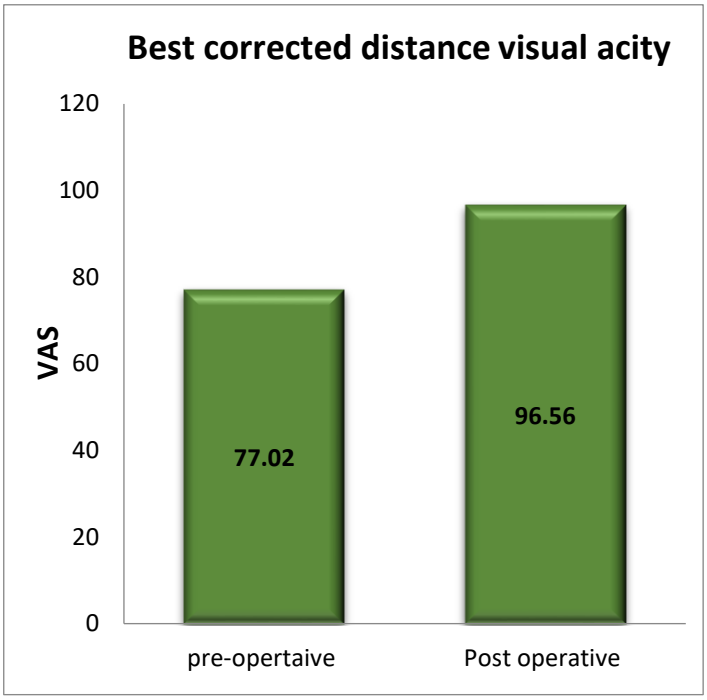
	Pre-operative	Post-operative
Visual acuity	**Mean±STD**	**Mean±STD**
Uncorrected distance Visual Acuity (UDVA)	72±23.89	91.51±10.68
Best distance corrected Visual Acuity (BDVA)	77.02±23.85	96.56±10.09

Graphical representation for Uncorrected distance Visual Acuity in Vas from pre and post-operative Ophthalmic Foldable Intraocular Lens-Hydrophobic treatment is given below:



The bar chart illustrates the mean distance uncorrected Visual acuity of operative eye values from the pre-operative stage to the post-operative follow-up visits for 144 subjects. It's been observed that the mean distance uncorrected Visual acuity of operative eye values in pre-operative visit is 72 which is increasing in post-operative visits, which means significant improvement in the subject vision.

Graphical representation for Best distance corrected Visual Acuity in Vas from pre and post-operative Ophthalmic Foldable Intraocular Lens-Hydrophobic treatment is given below:



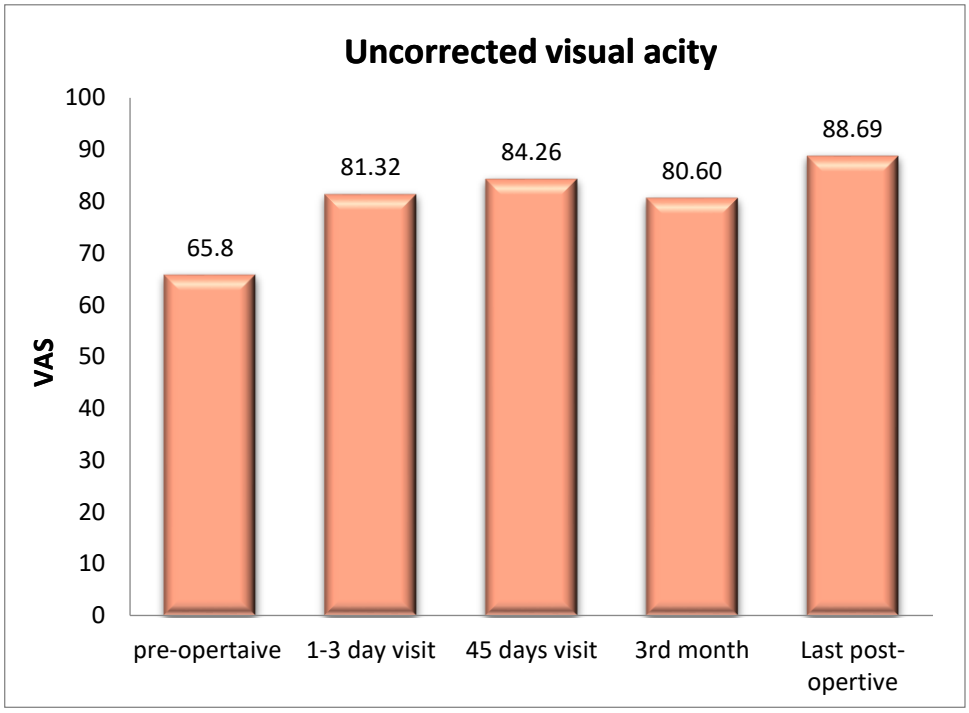
The bar chart illustrates the mean Best corrected Visual acuity of operative eye values from the pre-operative stage to the post-operative follow-up visits of 144 subjects. It's been observed that the mean distance Best corrected Visual acuity of operative eye value in pre-operative visit is 77.02, which is increasing in post-operative visit, which means significant improvement in the subject vision after implanting with our Hydrophobic lens.

M N Eye Hospital Pvt Ltd

Description for Visual Acuity in Vas in pre and post-operative Ophthalmic Foldable Intraocular Lens-Hydrophobic treatment is given below:

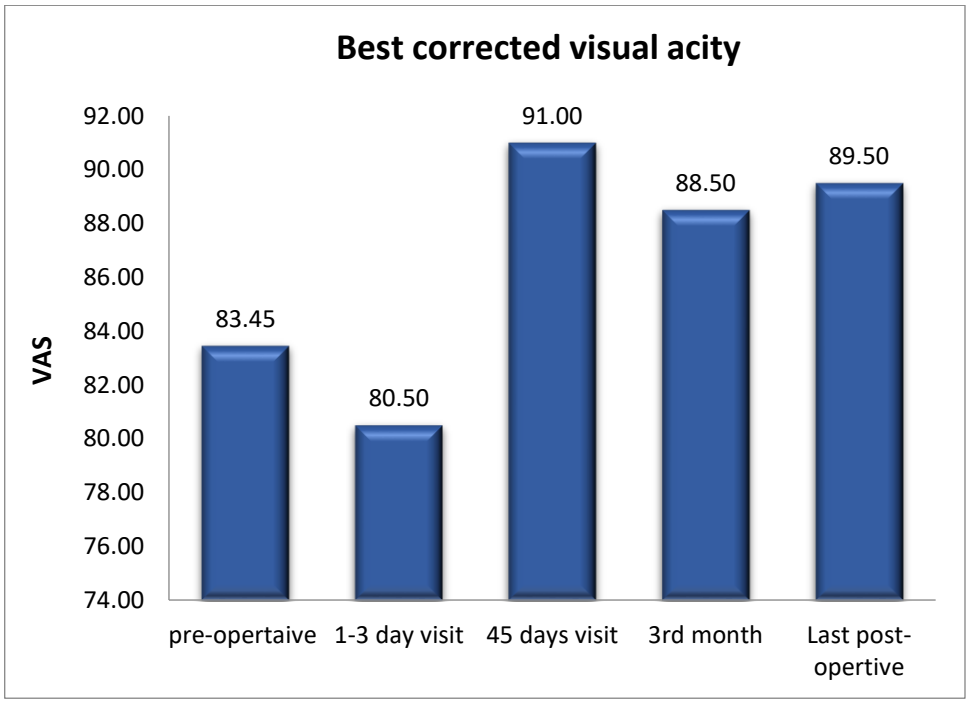
	Pre-Operative	1–3-day visit	45 days visit	3rd month visit	Last post-operative visit
Visual acuity	**Mean±STD**	**Mean±STD**	**Mean±STD**	**Mean±STD**	**Mean±STD**
Uncorrected Visual Acuity (UCVA)	65.8±22.44	81.32±10.51	84.26±9.63	80.60±13.18	88.69±3.04
Best corrected Visual Acuity (BCVA)	83.45±19.14	80.50±14.85	91.00±0.00	88.50±6.12	89.50±3.00

Graphical representation for Uncorrected distance Visual Acuity in Vas from pre and post-operative Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded treatment is given below:



The bar chart illustrates the mean distance uncorrected Visual acuity of operative eye values from the pre-operative stage to the post-operative follow-up visits of 59 subjects. It's been observed that the mean distance uncorrected Visual acuity of operative eye values in pre-operative visit is 65.8 which is increasing in all subsequent visits, which means significant improvement in the subject vision.

Graphical representation for best distance corrected Visual Acuity in Vas from pre and post-operative Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded treatment is given below:



The bar chart illustrates the mean Best corrected Visual acuity of operative eye values from the pre-operative stage to the post-operative follow-up visits of 59 subjects. It's been observed that the mean distance Best corrected Visual acuity of operative eye value in pre-operative visit is 83.45, which showed slight decrease in 1–3-day visit, but in all other subsequent visits it showed increment when compared to pre-operative value, which means significant improvement in the subject vision after implanting our hydrophobic lens.

2. Performance parameters Analysis

Dr. Kumaran eye Hospital

Performance parameters given below were analyzed during the study: Below parameters also observed for the subjects during the follow up post- surgery visits. The summary of the outcome is given below:

Parameter	Result
IOL Decentration	Not observed in 144 subjects
IOL tilt	Not observed in 144 subjects
IOL discoloration	Not observed in 144 subjects
IOL opacity	Not observed in 144 subjects

M N Eye Hospital Pvt Ltd

Performance parameters given below were analyzed during the study:

Parameter	Total
IOL Decentration	Not observed in 59 subjects
IOL tilt	Not observed in 59 subjects
IOL discoloration	Not observed in 59 subjects
IOL opacity	Not observed in 59 subjects

IOL Decentration, IOL tilt, IOL discoloration and IOL opacity were not observed in any of the subject participated from the above-mentioned study sites during the study period.

II. Safety Evaluation

Safety parameters given below were analyzed during the study for the subjects undergone cataract surgery with our hydrophobic lens:

a) Dr. Kumaran eye Hospital

Safety Parameters	Result
Intraocular Pressure	Unknown
Corneal Status	Normal
Inflammation	Not observed in 144 subjects
Cystoid macular oedema	Not observed in 144 subjects
Endophthalmitis	Not observed in 144 subjects
Pupillary block	Not observed in 144 subjects
Retinal detachment	Not observed in 144 subjects
Status of Posterior capsule	Intact in 144 subject

b) M N Eye Hospital Pvt Ltd

Safety Parameters	Result
Intraocular Pressure	14.7±3.3
Corneal Status	Normal
Inflammation	Not observed in 59 subjects
Cystoid macular oedema	Not observed in 59 subjects
Endophthalmitis	Not observed in 59 subjects
Pupillary block	Not observed in 59 subjects
Retinal detachment	Not observed in 59 subjects
Status of Posterior capsule	Intact in 59 subjects

None of the subjects participated in the study from two centres had shown any kind of safety related issues

5.5 An overall summary of the clinical performance and safety

- Vision Loss, infection/allergic reaction, severe inflammation - Toxic anterior segment syndrome, increased IOP, Haptic demolition or crack, Cloudy lens - Wound Leakage, Corneal Edema, Blurred Vision, develop glare, halos, double vision, decreased vision	Subject Device: 1. Ease of Insertion 2. Reduced Handling Problems 3. Reduced longer Unfolding Time 4. Satisfactory IOL Position 5. Significant improvement after surgery 6. Excellent Visual outcome 7. No Post operation Lens Opacification 8. Reduced chances of ACO / PCO Similar Device: 1. Good mechanical stability 2. Good uveal biocompatibility. 3. Low rates of posterior capsular opacification (PCO). 4. Including light-normalizing technology, along with its surface and edge characteristics, combine to provide unique advantages for the majority of patients undergoing lens replacement surgery. 5. IOLs provide very good optical clarity.

The Ophthalmic Foldable Hydrophobic Intra Ocular Lens_ Semi Preloaded complies with all the Safety and Performance requirements with respect to the intended use of the device from the Clinical Evaluation study. The clinical evaluation is complete and conforms to the general safety and performance requirements. The Clinical evidence is demonstrated with the relevant General Safety & Performance Requirements as per Annex I of MDR. Risk Mitigation has been established as per the guidelines of ISO 14971.

5.6 Ongoing or planned post-market clinical follow-up

We have planned for a prospective Post market clinical follow up study for the year 2023-2024.

6. Possible diagnostic or therapeutic alternatives

- PMMA (Polymethyl Methacrylate) Rigid IOLs
- Silicone IOLs
- Hydrophilic Acrylic IOLs

7. Suggested profile and training for users

Target Users: Ophthalmic surgeon

Ophthalmic surgeons are responsible for treating problems with the eye as well as diagnosing ailments and prescribing medicine for the eye. An Ophthalmic surgeon also performs surgical procedures on the eye.

There is no special user training is required. However, the device related directions for use information is provided in the Instruction for Use.

8. Reference to any Applicable standards and Guidelines

8.1 Applicable Harmonized Standards

#	Standard ID	Current Issue	Tittle
Quality Management System Requirements			
1.	EN ISO 13485	2016/AC:2018/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management Requirements			
2.	EN ISO 14971	2019/A11:2021	Medical devices – Application of risk management to medical devices (ISO 14971:2019)
Biological Risk Evaluation Requirements			
3.	EN ISO 10993-10	2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitisation (ISO 10993-10:2021)
4.	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Labels & Symbols Requirements			
5.	EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
Packaging Requirements			
6.	EN ISO 11607-1	2020/A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
7.	EN ISO 11607-2	2020/A1:2023	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
Sterility Test Requirements			
8.	EN ISO 11737-1	2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
9.	EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
EO Sterilization Requirements			
10.	EN ISO 11135	2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)

8.2 Other Applicable Standards

#	Standard ID	Current Issue	Tittle
Risk Management Requirements			
1.	EN ISO/TR 24971	2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
Usability			
2.	IEC 62366-1	2015/AMD 1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
Biological Risk Evaluation Requirements			
3.	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
4.	EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
5.	EN ISO 10993-5	2009/A11:2025	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
6.	EN ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
7.	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
Labels & Symbols Requirements			
8.	ISO 15223-1	2021 /Amd 1:2025	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific
Instructions For Use Requirements			
9.	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Medical Device "Non-active" Particular Standard Requirements			
10.	EN ISO 11979-1	2018	Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:2018)
11.	EN ISO 11979-2	2024	Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO 11979-2:2024)
12.	EN ISO 11979-3	2012	Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:2012)
13.	EN ISO 11979-4	2008/A1: 2012	Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information - Amendment 1 (ISO 11979-4:2008/Amd 1:2012)
14.	EN ISO 11979-5	2020	Ophthalmic implants - Intraocular lenses - Part 5: Biocompatibility (ISO 11979-5:2020)
15.	EN ISO 11979-6	2014	Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability testing (ISO 11979-6:2014)
16.	EN ISO 11979-7	2024	Ophthalmic implants - Intraocular lenses - Part 7:

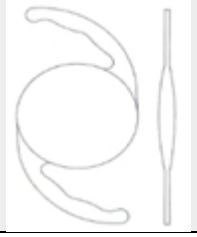
#	Standard ID	Current Issue	Tittle
			Clinical investigations of intraocular lenses for the correction of aphakia (ISO 11979-7:2024)
17.	EN ISO 11979-8	2017	Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2017)
Post Market Surveillance Requirements			
18.	EN ISO/ TR 20416	2020	Medical devices - post-market surveillance for manufacturers (ISO/TR 20416:2020)

8.3 Applicable Guidelines

#	Guideline	Current Issue	Title
1.	MEDDEV 2.7.1 Rev. 4	June 2016	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
2.	MEDDEV 2.5/5 Rev. 3	February 1998	Translation Procedure - Guidelines relating to the application of: The council directive 90/385/EEC on active implantable medical devices The council directive 93/42/EEC on medical devices
3.	MEDDEV 2.12-1 Rev. 8	January 2013	Guidance document - Market surveillance - Guidelines on a Medical Devices Vigilance System
4.	NB-MED 2.12/Rec. 1	February 2000	Post-Marketing Surveillance (PMS) post market/production
5.	MDCG 2021-24	October 2021	Guidance on classification of medical devices
6.	MDCG 2020-6	April 2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for Manufacturers and notified bodies
7.	MDCG 2018-1 Rev.4	April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
8.	MDCG 2020-7	April 2020	Post-market clinical follow-up (PMCF) Plan Template - A guide for manufacturers and notified bodies
9.	MDCG 2020-8	April 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies
10.	MDCG 2022-21	December 2022	Guidance on periodic safety update Report (PSUR) according to regulation (EU) 2017/745 (MDR)
11.	MDCG 2019-8 V2	March 2020	Guidance Document - Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
12.	MDCG 2019-9 Rev.1	March 2022	Summary of safety and clinical performance A guide for manufacturers and notified bodies
13.	MDCG 2021-11	8 June 2021	Guidance on Implant Card – Device types
14.	MDCG 2020-3 Rev.1	6 September 2023	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR - May 2023
15.	MDCG 2024-2	February 2024	MDCG 2024-2 Procedures for the updates of the European Medical Device Nomenclature

9. Product Technical specifications

Brand/Model – GALAXY SUPERPHOB – AE-01

Parameter	Specification
Optic Type	Monofocal
Optic Material	Hydrophobic Soft Acrylic (Polymer) - Yellow
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.5050
Optic Design	Biconvex
Haptic Material	Hydrophobic Soft Acrylic (Polymer)
Optic Diameter	6.00mm
Overall Length	13.00mm
Haptic Angle	0°
"A" Constant	118.8
Square Edge	360°
Diopter Range	-10.00D to +50.00D in steps of 0.50D
Diopter Increment	0.50D
Compatible Lens delivery system	Cartridge 2.2, 2.4 & 2.8
Sterilization	EO Gas
Intended Use	IOL can be defined as 'Optical Implants for the replacement of the human crystalline lens in the visual correction of aphakia (cataract)'. Intraocular lens functions as a refracting medium to replace the natural lens in the correction of cataract.
Attributes	Aphakic, Monofocal, Aspheric
Design (one per line) - Single piece or - Three piece or - multi piece	Single piece
Design (One per line) - Plate haptic - Loop haptic: C loop, J loop - Plate loop haptic - Other design	C Loop Haptic 
Location (One per line) - Capsular bag - Anterior chamber or Posterior chamber - Scleral or Iris or Sulcus Fixated	Capsular bag in posterior chamber
Device Intended User	Ophthalmic surgeon
Patient Population	Above age of one year (Male or Female)
Indications	- Monocular Cataract - Mature Cataract - Congenital Cataract - Immature cataract - Refractive lens (Exchange) Relex - Traumatic Cataract - Binocular cataract
Shelf Life	5 Years
Packing Contains	• One Sterile Hydrophobic Single Piece Equi Biconvex Foldable lens loaded in a Single use Cartridge • One Sterile Injector Delivery System

Parameter	Specification
	• Patient ID card • Implant Notification Card • Labels • Instruction for use

Brand/Model – GALAXY SUPERPHOB INFOCUS – AE INFO

Parameter	Specification
Optic Type	Multifocal
Optic Material	Hydrophobic Soft Acrylic (Polymer) - Yellow
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.5050
Optic Design	Biconvex
Haptic Material	Hydrophobic Soft Acrylic (Polymer)
Optic Diameter	6.00mm
Overall Length	13.00mm
Haptic Angle	0°
"A" Constant	118.8
Square Edge	360°
Diopter Range	-10.00D to +50.00D in steps of 0.50D
Diopter Increment	0.50D
Compatible Lens delivery system	Cartridge 2.2, 2.4 & 2.8
Sterilization	EO Gas
Intended Use	IOL can be defined as 'Optical Implants for the replacement of the human crystalline lens in the visual correction of aphakia (cataract)'. Intraocular lens functions as a refracting medium to replace the natural lens in the correction of cataract.
Attributes	Aphakic, Multifocal, Aspheric
Design (one per line) - Single piece or - Three piece or - multi piece	Single piece
Design (One per line) - Plate haptic - Loop haptic: C loop, J loop - Plate loop haptic - Other design	C Loop Haptic 
Location (One per line) - Capsular bag - Anterior chamber or Posterior chamber - Scleral or Iris or Sulcus Fixated	Capsular bag in posterior chamber
Device Intended User	Ophthalmic surgeon
Patient Population	Above age of one year (Male or Female)
Indications	- Monocular Cataract - Mature Cataract - Congenital Cataract - Immature cataract - Refractive lens (Exchange) Relex

Parameter	Specification
	- Traumatic Cataract - Binocular cataract
Shelf Life	5 Years
Packing Contains	• One Sterile Hydrophobic Single Piece Equi Biconvex Foldable lens loaded in a Single use Cartridge • One Sterile Injector Delivery System • Patient ID card • Implant Notification Card • Labels • Instruction for use

10. Revision history

SSCP Rev. No.	Date Issued	Change description	Rev. Validated by the NB
01	04.12.2023	Initial Release	☐ Yes Validation language: English ☐ No
02	20.01.2024	As per Internal review	☐ Yes Validation language: English ☐ No
03	19.11.2025	Yearly update	☐ Yes Validation language: English ☐ No