1.0 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.

2.0 Device identification and general information

2.1 Device Brand / Trade Name(s)

Product Name:	Ophthalmic Foldable Hydrophilic Lens
Brand/Proprietary Name:	Galaxy Fold
Model/Variants:	Center Fix, Center Fit, Ultrasmart & M-DIFF

2.2 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

2.3 Manufacturer's Single Registration Number (SRN)

US-MF-000014670

2.4 Basic UDI-DI

Ophthalmic Foldable Hydrophilic Lens - 08466600HPHILICGALAFJ2

2.5 Medical Device Nomenclature

EMDN Code: P030102100202 - IOLs, Aphakic, Multifocal, Aspheric, Hydrophilic Acrylic.
P030102090202 - IOLs, Aphakic, Monofocal, Aspherical, Hydrophilic Acrylic

2.6 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	Invasive – 08
Classification	IIb
Reference	In accordance with Annex VIII of EU Medical Device Regulation 2017/745

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

27/10/2017

2.8 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

2.9 NB Details

Name:	**DNV Product Assurance AS**
Address:	Veritasveien 1, 1363 Høvik, Norway
Phone:	+4767579900
Email:	medicalindia@dnv.com
Website:	www.dnv.com
Notified Body No.:	2460

2.10 Conformity Assessment Procedure

Conformity assessment procedure followed is Annexure IX.

2.11 Link to SSCP in website

The link for the Summary of Safety and Clinical Performance (SSCP) is provided below:

3.0 Intended use of the device

3.1 Intended Purpose

a) GALAXY FOLD - CENTER FIX & CENTER FIT

Galaxyfold IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. The following indications and contraindications are based on research of medical literature and are to be used only as guides. The list is indicative and not to be viewed as complete or comprehensive.

b) GALAXY FOLD - Ultra Smart®

Galaxyfold Ultrasmart IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. The following indications and contraindications are based on research of medical literature and are to be used only as guides. The list is indicative and not to be viewed as complete or comprehensive.

c) GALAXY FOLD - M-DIFF

Foldable lens acts as refracting medium by replacing natural crystalline lens during aphakia correction. Galaxy fold M-diff IOL provides clear vision at both near and far. Indications and contraindications listed here are collected from approved medical literatures to be used only as guidelines.

3.2 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)

3.3 Contraindications and/or Limitations

- Chronic Severe Uveitis
- Concomitant Severe Eye Disease
- Epithelial Dystrophy
- Glaucoma Problem
- Proliferative Diabetic Retinopathy
- Rubella Cataract
- Choroidal Haemorrhage
- Massive Vitreous Loss
- Microphthalmos

- Anirida
- Astigmatism

4.0 Device Description

4.1 Description of the Device

a) GALAXY FOLD - CENTER FIX & CENTER FIT

Intra Ocular Lenses are optical implants for the human crystalline lens in the visual correction of aphakia. The lens optic is lathe cut from HEMA blanks with UV blocking properties.

b) GALAXY FOLD - Ultra Smart®

Intra Ocular Lenses are optical implants for the human crystalline lens in the visual correction of aphakia. The lens optic is lathe cut from HEMA blanks with UV blocking properties.

c) GALAXY FOLD - M-DIFF

The Galaxyfold M-Diff sterile UV-absorbing Hydrophilic foldable single piece posterior chamber lens is an optical implant for the replacement of human crystalline lens in the visual correction of aphakia. These lenses have two point supporting haptics for easy centration and aspherical surface on posterior side and Refractive-Diffractive surface on anterior side.

4.1.1 Device Drawing

#	Variant Name	Image
1.	Center Fix	
2.	Center Fit	
3.	Ultrasmart	

4.	M-DIFF	

4.1.2 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.

4.1.3 Mode of Operation

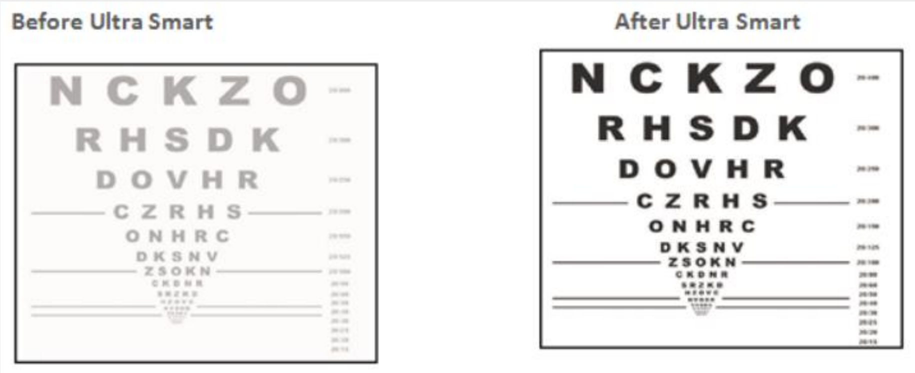
PLEASE examine the peel-pouch prior to opening to assure sterility. Any Damage to the peel-pouch should be viewed very seriously and the IOL inside might not be sterile. After proper examination, peel the pouch and remove the PP Cup carefully. Hold the PP Cup and peel the seal. Lift the PP Cup cover up to expose the IOL. Please NEVER soak or rinse the IOL in solutions. Do not use rubber gloves dusted with talc powder. It may cause irritation

4.1.4 Design Characteristics

Variant	Details
Center Fit	Galaxy Fold Center Fit is a single piece hydrophilic acrylic lens manufactured from ultrapure 26% hydrophilic material with excellent biocompatibility and low inflammatory response. The material is free of microvacuoles and glistening. Handling characteristics and unfolding are optimal for placement inside the capsular bag. • Lenses are lathe cut using nano precision machining technology and tumble polished to produce high quality optical surfaces. • Negative spherical aberration design on anterior surface improves contrast sensitivity and low light visual acuity compared with spherical IOLs. • 360-degree square edge design reduces the incidence of PCO and YAG capsulotomy rates. • The 4-haptics design enhances wider angle of equitorial contact and reliable centration inside the capsular bag.
Center Fix	Galaxy Fold Center Fix is a single piece hydrophilic acrylic lens manufactured from ultrapure 26% hydrophilic material with excellent biocompatibility and low inflammatory response. The material is free of microvacuoles and glistening. Handling characteristics and unfolding are optimal for placement inside the capsular bag. • Lenses are lathe cut using nano precision machining technology and tumble polished to produce high quality optical surfaces. • Negative spherical aberration design on anterior surface improves contrast sensitivity and low light visual acuity compared with spherical IOLs. • 360-degree square edge design reduces the incidence of PCO and YAG capsulotomy rates. • The closed loop haptics design ensures excellent centration and stability inside the capsular bag.
Ultrasmart	Galaxy Fold Ultrasmart is a single piece hydrophilic acrylic lens manufactured from ultrapure 26% hydrophilic material with excellent biocompatibility and low inflammatory response. The material is free of microvacuoles and glistening. Handling characteristics and unfolding are optimal for placement inside the capsular bag. • Lenses are lathe cut using nano precision machining technology and tumble polished to produce high quality optical surfaces.

<table>
<tr><th>Variant</th><th>Details</th></tr>
<tr><td></td><td>

Negative spherical aberration design on anterior surface improves contrast sensitivity and low light visual acuity compared with spherical IOLs.
360-degree square edge design reduces the incidence of PCO and YAG capsulotomy rates.
The 4-haptics design enhances wider angle of equitorial contact and reliable centration inside the capsular bag.



</td></tr>
</table>

4.1.5 Method of Sterilization

Steam sterilization

4.1.6 Device Lifetime/Stability

The Life time of the Ophthalmic Foldable Hydrophilic Lens is 15 Years after implantation

4.1.7 Information about the constituents

a. Device with Medicinal Product

Ophthalmic Foldable Hydrophilic Lens does not incorporate medicinal substances. Hence this declaration is not applicable.

b. Device with Human or Animal Origin Tissues

Ophthalmic Foldable Hydrophilic Lens 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

Ophthalmic Foldable Hydrophilic Lens 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)

Ophthalmic Foldable Hydrophilic Lens does not impact any Carcinogenic, Mutagenic or Toxic to reproduction (CMR). Hence this declaration is not applicable.

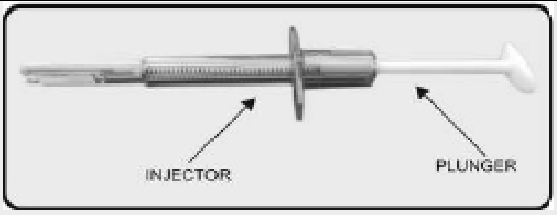
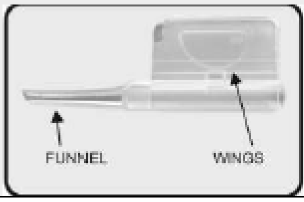
e. Materials could result sensitisation or an allergic reaction to patient/user

HEMA – Hydroxyethyl methacrylate

4.2 Reference to previous generation(s) or variants

Legacy Device Name:	Ophthalmic Foldable Hydrophilic Lens
Brand/Proprietary Name:	GALAXY FOLD
Models/Variants:	CENTERFIX, CENTERFIT, ULTRASMART, ULTRASMART-M, MDIFF
93/42/EEC (MDD) Cert. No.:	Certificate# 11330-2017-CE-IND-NA-PS Rev.1.0 Expiry Date: 25 October 2021
Notified Body Details:	DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway
Is any significant difference between Legacy Device & Device Under Evaluation?	No difference in device description, intended purpose, medical indications, target user, target patient population, side-effects, contraindications and raw materials used as part of the manufacturing.

4.3 Accessories Details

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

4.4 Combination with other Medical Devices

Ophthalmic Foldable Hydrophilic Lens is not used with any other medical device. Hence this declaration is not applicable.

5.0 Risks and warnings

5.1 Residual risks and undesirable side effects

- **Residual Risks**

- Vision Loss
- Inflammation, Optic Decentration, Posterior Capsule Rent, TASS (Toxic anterior segment syndrome)
- Wound Leakage, Corneal Edema, Blurred Vision

- **Potential Hazards**

The relevant hazards and side effects of Intra Ocular Lens are essentially the same as (but not limited to) those of routine cataract extraction. These include the following: -

- Intra Ocular Foreign Body Debris
- Temporary Corneal Edema
- Secondary cataract formation
- Vitreous Herniation in the formation
- Mispositioned Lens
- Aphakic Glaucoma
- Temporary Flat Anterior Chamber
- Retinal Detachment
- Lens Implants Loop Amputation
- Endothelial Corneal Dystrophy Anterior Chamber Infection
- Pupillary Block
- Corneal Dystrophy
- Post operative Posterior capsule opacification (PCO)

5.2 Warnings

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

- Do Not Resterilise. Reserialisation 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.

5.3 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 Hydrophilic Lens. Hence FSCA or FSN is not applicable.

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

6.1 Summary of clinical data related to similar device, if applicable

The conformity of the device was also assessed and endorsed on the basis of similarity. The similar device details are given below:

The Ophthalmic Foldable Hydrophilic Lens belongs to the existing and proven technology in the current market. Ophthalmic Foldable Hydrophilic Lens has similar devices in the current market with similar technology and design for the same intended use purpose. The similarities demonstration is carried out in 5 aspects.

- General Comparison
- Regulatory Comparison
- Clinical Comparison
- Technical Comparison
- Biological Comparison

The following similar device is selected for the similarities demonstration and is already proven in the current market:

S.no	Subjective Device	Similar Device
1.	Galaxy Fold- CENTER FIX	Superflex Aspheric-920H by Rayner Intraocular Lenses Ltd
2.	Galaxy Fold- CENTER FIT	ASPIRA- Aqa by Human Optics AG, Germany
3.	Galaxy Fold- Ultrasmart	MICRIOL PLUS- MP611 by Care Group
4.	Galaxy Fold- M-DIFF	DIFF- aA by Human Optics AG, Germany

Features	Similar Device of CENTER FIX	Similar Device of CENTER FIT	Similar Device of Ultrasmart	Similar Device of M-DIFF
Manufacturer	Rayner Intraocular Lenses Ltd.	Human Optics AG, Germany	Care Group	Human Optics AG, Germany
Product Name	Ophthalmic Foldable Hydrophilic lens	Ophthalmic Foldable Hydrophilic lens	Ophthalmic Foldable Hydrophilic lens	Ophthalmic Foldable Hydrophilic lens
Brand Name	Superflex Aspheric – 920H	ASPIRA- Aqa	MICRIOL- PLUS	DIFF- aA
BASIC UDI-DI	Information not available	Information not available	Information not available	Information not available
SSCP in EUDAMED	Not Available, hence a summary of the clinical data pertaining to the similar device is given below	---	Not Available, hence a summary of the clinical data pertaining to the similar device is given below	---

The conformity assessment of the device has been conducted and endorsed by the Notified Body on the basis of Similar Device Comparison.

Study-1

Title	The effect of cataract surgery on salivary melatonin and sleep quality in aging people
Source of link	https://pubmed.ncbi.nlm.nih.gov/27384816
Device Name	The aspheric Monofocal neutral ultraviolet-only (UV-only) blocking IOLs Superflex Aspheric 920H; Rayner, England
Literature Objective	In the present study, we use salivary melatonin concentration as a convenient, non-invasive, objective and reliable biomarker for circadian rhythm assessment, combining with sleep questionnaires, to investigate the effect of cataract surgery on circadian rhythm.
Methods	In this study, we assessed 30 binocular age-related nuclear cataract patients (aged 72.5 ± 7.2, 16 female) who were eligible for cataract surgery. All the patients underwent phacoemulsification cataract extraction and neutral ultraviolet-only blocking intraocular lens (IOLs) implantation. Visual functions including best-corrected visual acuity (BCVA), color perception and dark adaptation were assessed. Salivary samples were collected at 1-hour interval from 19:00 to 23:00 48 hours before and after surgery. Salivary melatonin concentration was measured and dim light melatonin onset (DLMO) was calculated subsequently. Sleep quality and daytime alertness were assessed before and a month after surgery using Pittsburgh Sleep Quality Index (PSQI) and Epworth Sleepiness Scale (ESS).
Results	All the operated eyes demonstrated significant improvements in BCVA, color perception and dark adaptation after cataract surgery. Salivary melatonin concentration at 23:00 was significantly increased after surgery ($P < 0.001$). However, the average DLMO did not change significantly after surgery. In addition, PSQI and ESS scores were significantly decreased a month after surgery ($P = 0.027$, $P < 0.001$, respectively).
Conclusion	In conclusion, cataract surgery with neutral UV-only blocking IOL implantation improves visual functions in the elderly. Meanwhile, it increases blue light transmission, which might lead to an increase in night time melatonin concentration and improvement in sleep quality.

Study- 2

Title	Visual Outcome After Microcoaxial Phacoemulsification With Micriol Plus Lens Implantation
Source of link	https://www.semanticscholar.org/paper/VISUAL-OUTCOME-AFTER-MICROCOAXIAL-WITH-MICRIOL-PLUS-Mir-Shafi/f09b05682e055261f0cef95e82b0c2379d179bd8
Device Name	MICRIOL PLUS lens from Care Group
Literature Objective	Study carried out in a tertiary care eye institute in North India with the aim of evaluating the visual outcome after Microcoaxial Phacoemulsification with MICRIOL PLUS lens implantation as well as to study the intraoperative and postoperative complications associated with the procedure.
Methods	Prospective study conducted in one hundred cases over a period of one year. Patients with grade 1 to 3 nuclear and cortico-nuclear cataracts were included in the study after undergoing complete ophthalmic evaluation. Each patient underwent Microcoaxial Phacoemulsification using incision size of 2.2 mm and MICRIOL PLUS lens was implanted in each case using 'D' cartridge. Patients were followed up for a period of 6 months and visual acuity, slit lamp

	biomicroscopy, IOL centration, capsule opacification were noted during follow up.
Results	Microcoaxial Phacoemulsification was successfully performed in all 100 eyes. 93 % patients achieved a BCVA of 6/9 or better over a 6 month follow-up, the procedure being associated with low intraoperative and postoperative complications.
Conclusion	Microcoaxial Phacoemulsification with MICRIOL PLUS lens is a safe and cost effective alternative surgical procedure for management of cataracts with excellent postoperative visual acuity and few intraoperative and postoperative complications.

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

Not Applicable

6.3 Summary of clinical data from other sources, if applicable

- **Literature evidence - Pertinent Literatures for Appraisal**

#	Literature#	Source Link	Literature Title
1.	L1	https://pubmed.ncbi.nlm.nih.gov/15162271/	Clinical outcomes and complications of intraocular lens exchange in patients with opacified hydrophilic acrylic lenses SC600-2
2.	L2	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4334325/	Opacification of hydrophilic intraocular lenses after Descemet stripping automated endothelial keratoplasty
3.	L3	https://pubmed.ncbi.nlm.nih.gov/32527240/	Clinical safety and efficacy of a hydrophilic acrylic intraocular lens in a real-world population: a 1-year follow-up retro-prospective study
4.	L4	https://pubmed.ncbi.nlm.nih.gov/17671936/	Comparison of sulcus implantation of single-piece hydrophilic foldable acrylic and polymethylmethacrylate intraocular lenses in eyes with posterior capsule tear during phacoemulsification surgery
5.	L5	https://doi.org/10.1371/journal.pone.0220498	Effect of AcrySof versus other intraocular lens properties on the risk of Nd:YAG capsulotomy after cataract surgery: A systematic literature review and network meta-analysis
6.	L7	https://pubmed.ncbi.nlm.nih.gov/15522377/	Late postoperative opacification of a hydrophilic acrylic (hydrogel) intraocular lens: a clinicopathological analysis of 106 explants
7.	L8	https://pubmed.ncbi.nlm.nih.gov/14967277/	Late postoperative opacification of MemoryLens hydrophilic acrylic intraocular lenses: case series and Review
8.	L9	https://pubmed.ncbi.nlm.nih.gov/31856993/	Localized calcification of hydrophilic acrylic intraocular lenses after posterior segment procedures
9.	L10	https://pubmed.ncbi.nlm.nih.gov/218793	Hydrophilic acrylic intraocular lens optic

#	Literature#	Source Link	Literature Title
		09/	opacification in a diabetic patient
10.	L11	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5406635/	Long-term rotational stability and visual outcomes of a single-piece hydrophilic acrylic toric IOL: a 1.5-year follow-up
11.	L12	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5859398/	Effect of number and position of intraocular lens haptics on anterior Capsule contraction: a randomized, prospective trial
12.	L13	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6943283/	Severe intraocular lens opacification after scleral suturing in a patient with retinitis pigmentosa
13.	L14	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6922436/	Subsurface calcification of hydrophilic refractive multifocal intraocular lenses with a hydrophobic surface
14.	L16	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3498857/	Hydrophilic Acrylic versus PMMA Intraocular Lens Implantation in Pediatric Cataract Surgery
15.	L17	http://docplayer.net/42916212-Prospective-clinical-trial-of-mediflex-posterior-chamber-acrylic-intraocular-lens-1-year-results.html	Prospective Clinical Trial of Mediflex Posterior Chamber Acrylic Intraocular Lens
16.	L19	https://pubmed.ncbi.nlm.nih.gov/17189798/	Three-hundred-sixty degree barrier effect of a square-edged and an enhanced-edge intraocular lens on centripetal lens epithelial cell migration Two-year results
17.	L20	https://pubmed.ncbi.nlm.nih.gov/26100954/	Glistenings 9 years after phacoemulsification in hydrophobic and hydrophilic acrylic intraocular lenses
18.	L22	https://pubmed.ncbi.nlm.nih.gov/17397735/	Effect of primary posterior continuous curvilinear capsulorhexis on clinical performance of ACR6D SE single-piece hydrophilic acrylic intraocular lenses
19.	L23	https://pubmed.ncbi.nlm.nih.gov/17276267/	Clinical effects of primary posterior continuous curvilinear capsulorhexis in eyes with single-piece hydrophilic acrylic intraocular lenses with and without haptic angulation
20.	L24	https://pubmed.ncbi.nlm.nih.gov/19631134/	Complications of sulcus placement of single-piece acrylic intraocular lenses: recommendations for backup IOL implantation following posterior capsule rupture
21.	L27	https://pubmed.ncbi.nlm.nih.gov/21236406/	Evaluation of Intraocular Lens Tilt With Anterior Segment Optical Coherence Tomography
22.	L28	https://pubmed.ncbi.nlm.nih.gov/27236574/	Optic surface changes in Intraocular lens scaffold: An ex vivo study
23.	L29	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7276164/	Intraoperative Evaluation of Phacoemulsification Cataract Surgery with and without the Use of Ophthalmic Viscosurgical Devices
24.	L30	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6376833/	Perceived difficulties and complications in learners of phacoemulsification: A principal

#	Literature#	Source Link	Literature Title
			component analysis model
25.	L32	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6727723/	Rotation versus non-rotation of intraocular lens for prevention of posterior capsular opacification
26.	L33	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3729577/	Effect of anterior capsular polishing on the rate of posterior capsule opacification: A retrospective analytical study
27.	L34	https://pubmed.ncbi.nlm.nih.gov/26605358/	Clinical outcomes with a new micro incisional diffractive multifocal IOL
28.	L35	https://pubmed.ncbi.nlm.nih.gov/24321599/	Intermediate term follow-up after a single-piece acrylic intraocular lens implantation in the ciliary sulcus- a cross-sectional study
29.	L36	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3782640/	Comparison of a hydrophilic and a hydrophobic apodized diffractive multifocal intraocular lens
30.	L37	https://pubmed.ncbi.nlm.nih.gov/32760851/	Variation in intraocular lens calcification under different environmental conditions in eyes with supplementary sulcus-supported lenses
31.	L38	https://www.semanticscholar.org/paper/VISUAL-OUTCOME-AFTER-MICROCOAXIAL-WITH-MICRIOL-PLUS-Mir-Shafi/f09b05682e055261f0cef95e82b0c2379d179bd8	Visual outcome after microcoaxial phacoemulsification With micriol plus lens implantation
32.	L39	https://pubmed.ncbi.nlm.nih.gov/27384816	The effect of cataract surgery on salivary melatonin and sleep quality in aging people
33.	L40	https://pubmed.ncbi.nlm.nih.gov/40142780/#:~:text=Conclusions%3A%20Hydrophilic%20IOLs%20can%20be,of%20the%20lenses%20were%20explanted	Safety of One-Piece Hydrophilic Acrylic Intraocular Lenses in the Ciliary Sulcus
34.	L41	https://pubmed.ncbi.nlm.nih.gov/38918765/	Clinical results with a multifocal intraocular lens with a novel optical design

Refer Section 4.5 of CER (CER-GF-01) for the detailed literature summary and literature appraisal.

6.4 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:

Overall, 58 subjects were implanted with Ophthalmic Foldable Hydrophilic Lens who have completed follow up till visit 5(twelve months).

Among 58 subjects, 16(28%) were male and 42(72%) were female. The population at risk for developing visually-disabling cataracts and needing cataract surgery is typically the elderly
From the result of 58 subjects, the Best Corrected Distant Visual acuity from Pre visit to 12th month visit shows the significant improvement after implantation of the Ophthalmic Foldable Hydrophilic Lens. BCDVA has increased from 54.41 mean value to 98.29 mean value on the 12th month visit, which represents an improvement in the patient's ability to see object clearly at a distance.

The mean of Keratometry of Ophthalmic Foldable Hydrophilic Lens shows that the curvature of the anterior surface of the cornea is within the normal range in both pre and post operative conditions. It means the curvature of the anterior surface of the cornea is not affected by insertion of IOL in subjects.
There were no new risks identified from the PMCF study for the products hence there was no addition to the residual risks which we have already identified in the Risk Management Report and that is been mitigated and are acceptable when weighed against the benefits to the patient. None of the subject had reported safety related issues and there were no adverse events reported.

6.5 An overall summary of the clinical performance and safety

Clinical and Medical Benefits identified	1. Increased Visual effect for distance objects 2. Decreased side effects 3. Decreased Post-operative effects 4. Less dysphotopsia 5. Good biocompatibility 6. Good optical clarity 7. Resistance to damage during insertion 8. Less susceptibility to bio-contamination

The Ophthalmic Foldable Hydrophilic Lens 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.

6.6 Ongoing or planned post-market clinical follow-up

N/A.

7.0 Possible diagnostic or therapeutic alternatives

- Hydrophobic Acrylic Foldable IOL
- Multifocal IOL
- Toric IOL
- Anterior Chamber IOL

8.0 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.

9.0 Reference to any harmonised standards and CS applied

9.1 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)

9.2 Applicable Non-Harmonized 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)
Steam Sterilization Requirements			
10.	EN ISO 17665	2024	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)
Medical Device "Non-active" Particular Standard Requirements			
11.	EN ISO 11979-1	2018	Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:2018)
12.	EN ISO 11979-2	2024	Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods (ISO 11979-2:2024)
13.	EN ISO 11979-3	2012	Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:2012)
14.	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)
15.	EN ISO 11979-5	2020	Ophthalmic implants - Intraocular lenses - Part 5:

#	Standard ID	Current Issue	Tittle
			Biocompatibility (ISO 11979-5:2020)
16.	EN ISO 11979-6	2014	Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability testing (ISO 11979-6:2014)
17.	EN ISO 11979-7	2024	Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia (ISO 11979-7:2024)
18.	EN ISO 11979-8	2017	Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2017)
Post Market Surveillance Requirements			
19.	EN ISO/ TR 20416	2020	Medical devices - post-market surveillance for manufacturers (ISO/TR 20416:2020)

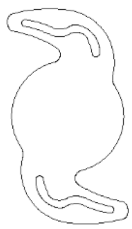
9.3 Applicable Guidelines

#	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

#	Guideline	Current Issue	Title
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

9.4 Product Technical specifications

9.4.1 Variant/Model – Center Fix

Parameter	Specification
Optic Type	Monofocal
Optic Material	HEMA – Hydroxyethyl methacrylate (Clear)
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.46
Optic Design	Biconvex
Haptic Material	HEMA – Hydroxyethyl methacrylate
Optic Diameter	6.10mm
Overall Length	12.25mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	-10.00 D to +50.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Compatible Lens delivery system	DIS-2.8, DPIS-2.4 & DIS-2.2
Sterilization	Moist Heat
Intended Use	Galaxyfold IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. The following indications and contraindications are based on research of medical literature and are to be used only as guides. The list is indicative and not to be viewed as complete or comprehensive
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 Closed 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

Parameter	Specification
Patient Population	Adults (Male or Female)
Indications	• Monocular Cataract • Mature Cataract • Congenital Cataract • Occupational Needs • Traumatic Cataract
Shelf Life	4 Years
Packing Contains	Mono carton contains • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Patient ID card • Implant Notification Card • Labels • Information for use

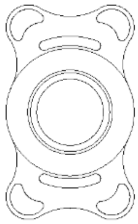
9.4.2 Variant/Model – Center Fit

Parameter	Specification
Optic Type	Monofocal
Optic Material	HEMA – Hydroxyethyl methacrylate (Clear)
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.46
Optic Design	Biconvex
Haptic Material	HEMA – Hydroxyethyl methacrylate
Optic Diameter	6.10mm
Overall Length	11.00mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	-10.00 D to +50.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Compatible Lens delivery system	DIS-2.8, DPIS-2.4 & DIS-2.2
Sterilization	Moist Heat
Intended Use	Galaxyfold IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. The following indications and contraindications are based on research of medical literature and are to be used only as guides. The list is indicative and not to be viewed as complete or comprehensive
Attributes	Aphakic, Monofocal, Aspheric
Design (one per line) - Single piece or - Three piece or - multi piece	Single Piece

Parameter	Specification
Design (One per line) - Plate haptic - Loop haptic: C loop, J loop - Plate loop haptic - Other design	Plate 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	Adults (Male or Female)
Indications	• Monocular Cataract • Mature Cataract • Congenital Cataract • Occupational Needs • Traumatic Cataract
Shelf Life	4 Years
Packing Contains	Mono carton contains • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Patient ID card • Implant Notification Card • Labels • Information for use

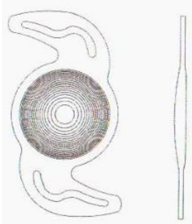
9.4.3 Variant/Model – Ultrasmart

Parameter	Specification
Optic Type	Monofocal
Optic Material	HEMA – Hydroxyethyl methacrylate (Clear)
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.46
Optic Design	Biconvex
Haptic Material	HEMA – Hydroxyethyl methacrylate
Optic Diameter	6.00mm
Overall Length	11.00mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	-10.00 D to +50.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Compatible Lens delivery system	DIS-2.8, DPIS-2.4 & DIS-2.2
Sterilization	Moist Heat
Intended Use	Galaxyfold Ultrasmart IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. The following indications and contraindications are based on research of medical

Parameter	Specification
	literature and are to be used only as guides. The list is indicative and not to be viewed as complete or comprehensive.
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	Plate 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	Adults (Male or Female)
Indications	• Monocular Cataract • Mature Cataract • Congenital Cataract • Occupational Needs • Traumatic Cataract
Shelf Life	4 Years
Packing Contains	Mono carton contains • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Patient ID card • Implant Notification Card • Labels • Information for use

9.4.4 Variant/Model – M-DIFF

Parameter	Specification
Optic Type	Multifocal
Optic Material	HEMA – Hydroxyethyl methacrylate (Clear)
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.46
Optic Design	Biconvex
Haptic Material	HEMA – Hydroxyethyl methacrylate
Optic Diameter	6.00mm
Overall Length	12.50mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°

Parameter	Specification
Diopter Range	-10.00 D to +50.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Compatible Lens delivery system	DIS-2.8, DPIS-2.4 & DIS-2.2
Sterilization	Moist Heat
Intended Use	Foldable lens acts as refracting medium by replacing natural crystalline lens during aphakia correction. Galaxy fold M-diff IOL provides clear vision at both near and far. Indications and contraindications listed here are collected from approved medical literatures to be used only as guidelines.
Attributes	Aphakic, Multifocal, Aspheric
6.10 mm	6.10 mm
Design (One per line) - Plate haptic - Loop haptic: C loop, J loop - Plate loop haptic - Other design	C Loop Closed 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	Adults (Male or Female)
Indications	• Monocular Cataract • Mature Cataract • Congenital Cataract • Occupational Needs • Traumatic Cataract
Shelf Life	4 Years
Packing Contains	Mono carton contains • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Patient ID card • Implant Notification Card • Labels • Information for use

10.0 Revision history

SSCP Rev. No.	Date Issued	Change description	Rev. Validated by the NB
01	29.12.2023	Initial Release	☐ Yes Validation language: English ☐ No
02	20.01.2024	Updated as per internal review	☐ Yes Validation language: English ☐ No
03	07.05.2025	Updated as per TR comment Section 4.1 Description of device Section 9.0 reference to any harmonised standards and cs	☐ Yes Validation language: English ☐ No

		applied Section 9.4 Product Technical specifications	
04	13.09.2025	1. Conformity assessment procedure with annex number added in section 2.10 2. Statement if conformity of the device was assessed and endorsed by the NB on the basis of equivalence is updated in section 6.1 3. Possible diagnostic or therapeutic alternatives is updated in section 7 4. Standard is revised in section 9. 5. PMCF plan summary is updated in section 6.4 6. Link to SSCP is provided in section 2.11	☐ Yes Validation language: English ☐ No