AI OPTICS PRIVATE LIMITED

SUMMARY OF CLINICAL AND SAFETY PERFORMANCE

FOR USERS AND HEALTHCARE PROFESSIONALS

Ref. Guidance:

MDCG 2019-9
Summary of safety and clinical performance, A guide for manufacturers and notified bodies

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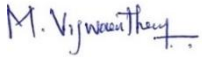
Approvals	Name	Designation	Signature	Date
Prepared By	M.Viswanathan	Regulatory Manager		10.11.2025
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Approved By	M.Subramaniam	Plant Manager		10.11.2025

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.

1.0 Device identification and general information

1.1 Device Brand / Trade Name(s)

Device Name: FOLDABLE HYDROPHILIC INTRAOCULAR LENS- APHAKIC

Brands and Models:

Brands	Models	Attributes
Acryfold	601, 502, 701, Ultrasmart	Aphakic, Monofocal, Clear
	601Y	Aphakic, Monofocal, Yellow
Naspro	Nas207	Aphakic, Monofocal, Clear
NasproBBY	Nasy207	Aphakic, Monofocal, Yellow
CM-T FLEX	Acryflex T	Aphakic, Monofocal, Clear
Multidiff	MFD605	Aphakic, Multifocal, Clear
	MFDY605	Aphakic, Multifocal, Yellow
Multidiff Trifit	MFDY705	Aphakic, Multifocal, Yellow

1.4 Manufacturer's Name & Address

Name:	AI Optics Private Limited
Address:	84/1, Aavin Dairy Road, SIDCO Industrial Estate, Ambattur, Chennai-600098.
Email:	info@appasamy.com
Website:	www.appasamy.com
SRN	IN-MF-000013253

1.5 Basic UDI-DI

#	Variant Name	Device Identifier (DI)
1.	ACRYFOLD – 601, 502, 701, ULTRASMART, 601Y	Hydrophilic Aphakic Foldable Intraocular lens 89043129APHAKICNU
2.	NASPRO – NAS207	
3.	NASPROBBY - NASY207	
4.	CM-T FLEX - Acryflex T	

5.	MULTIDIFF-MFD605, MFDY605	
6.	MULTIDIFF TRIFIT- MFDY705	

1.6 Medical Device Nomenclature

EMDN Code	Description
P030102090202	IOLs, APHAKIC, MONOFOCAL, ASPHERICAL, HYDROPHILIC ACRYLIC
P030102100202	IOLs, APHAKIC, MULTIFOCAL, ASPHERICAL, HYDROPHILIC ACRYLIC

1.7 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

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

18 July 2018

1.9 Authorised Representative

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

1.10 NB Details

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

2.0 Intended use of the device

2.1 Intended Purpose

FOR MONO FOCAL

(ACRYFOD, NASPRO, NASPRO BBY)

It 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.

(CM-T FLEX)

It is intended to be positioned in the sulcus in the bed of the sclera pocket and covered with a scleral mat by means of a special anchor with a self-locking system, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.

It is suitable for aphakic eyes, without a capsular bag. its anchoring to the scleral tissue using special anchors without the need for stitches, which simplifies surgery and greatly reduces its duration. It is not placed in the capsular bag. Instead, it is placed in the scleral who do not have an intact capsular bag or have a damaged capsular bag.

FOR MULTI FOCAL

(MULTIDIFF)

It 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. It provides clear vision at both near and far.

(MULTIDIFF TRIFIT)

It 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. It provides clear vision for distance, intermediate and near.

2.2 Indications & Target Populations

Medical Indications:

FOR MONO FOCAL

(ACRYFOD, NASPRO, NASPRO BBY)

IOL indicated for the replacement of the human lens to achieve visual correction of aphakia following cataract (congenital or traumatic or senile cataract) surgery. These lenses are intended for placement in the capsular bag.

(CM-T FLEX)

- Aphakia
- Shallow anterior chamber (<2.8mm)
- Congenital eye abnormality

- Pseudophakic patients with malpositioned, subluxated or unstable capsular fixated intraocular lens
- Inability to achieve secure placement in the designed location e.g. due to absence of a secure peripheral anterior capsule, absence of intactzonules, or irregular anatomy of the ciliary sulcus
- Corneal decompensation
- Microphthalmia
- Narrow angle, i.e. <Schaefer grade 2
- Pigment dispersion syndrome

FOR MULTIFOCAL

(MULTIDIFF & MULTIDIFF TRIFIT)

IOL indicated for the replacement of the human lens to achieve visual correction of aphakia following cataract (congenital or traumatic or senile cataract) surgery. These lenses are intended for placement in the capsular bag.

Target Population(s):

Adults

2.3 Contraindications and/or Limitations

FOR MONO FOCAL

(ACRYFOD, NASPRO, NASPRO BBY)

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected:

- Microphthalmia
- Active ocular diseases (Chronic severe uveitis, Proliferative diabetic retinopathy, chronic glaucoma not responsive to medication)
- Corneal de-compensation or endothelial insufficiency.
- Corneal Opacification.

(CM-T FLEX)

- Apart from non- specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected:
- Corneal damage or edema
- Secondary glaucoma
- Uveitis
- Intraocular Infection
- Hermorrhage
- Endophthalmitis
- Asthenopic discomfort, adaptional difficulties

- Reduced Vision at night or in poor visibility conditions
- Perception of halos or radial lines around point sources of light
- Dissatisfactory visual outcome due to incorrect IOL refraction
- Cystoid macular edema
- Pupillary block
- Iris trauma
- IOL exchange or extraction
- Postoperative opacification/calcification of the IOL
- Reduced Contrast sensitivity

FOR MULTIFOCAL

(MULTIDIFF & MULTIDIFF TRIFIT)

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected:

- Microphthalmia
- Active ocular diseases (Chronic severe uveitis, Proliferative diabetic retinopathy, chronic glaucoma not responsive to medication)
- Corneal de-compensation or endothelial insufficiency.
- Corneal Opacification.
- Children under the age of 18 years

3.0 Device Description

3.1 Description of the Device

FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC

FOR MONO FOCAL

(ACRYFOD, NASPRO, NASPRO BBY)

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. The HEMA IOLs are designed to be surgically implanted into the capsular bag of the human eye as a replacement for the crystalline lens Phacoemulsification.

A Single Piece IOL is a device in which the haptic is continuous with the HEMA optic and fabricated from the same material. The IOL are divided in two zones - the central clear optic (which acts as visual zone) and the peripheral haptic (which helps the lens to stay in position).

(CM-T FLEX)

Intra Ocular Lenses are optical for the human crystalline lens in the visual correction of aphakia. CM-T-Flex Intra Ocular Lenses is a single piece, sterile, foldable, hydrophilic acrylic optical device.

FOR MULTIFOCAL

(MULTIDIFF)

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. The HEMA IOLs are designed to be surgically implanted into the capsular bag of the human eye as a replacement for the crystalline lens Phacoemulsification.

A Single Piece IOL is a device in which the haptic is continuous with the HEMA optic and fabricated from the same material. The IOL are divided in two zones - the central clear optic (which acts as visual zone) and the peripheral haptic (which helps the lens to stay in position).

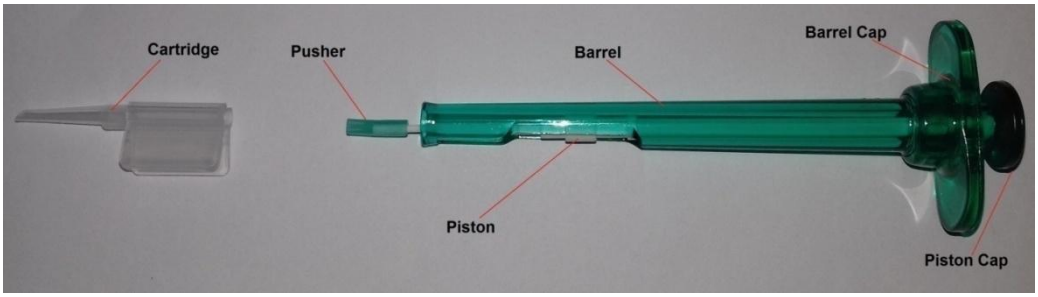
Diffractive used as a basis for the determination of light distribution in multifocal diffractive IOLs. It splits the light between the far & near vision; The lens provides one optical power for distance vision and a separate lens power for near vision. So, it rectifies the Distance and Near Vision in the optical system. Biconvex and special haptic design with slots prevents post-operative complications such as buckling or anteroposterior movement of the lens.

(MULTIDIFF TRIFIT)

The Multidiff Trifit 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.

Multidiff Trifit is available in variable diopters ranging from 0 to 35 diopters with the increment of 0.5 D which are inspected by higher end laser interferometers. These lenses have four point supporting haptics for easy centration and aspherical surface on posterior side and Refractive-Diffractive surface on anterior surface. This feature helps to the patient for reading without spectacle. Multidiff Trifit provides clear vision for distance, intermediate and near. The add power for near vision is +3.5D and for the intermediate vision it is +1.65D.

The lens is supplied with and without Disposable Injector System.



The lens delivery system is sterile Single Use Disposable Injector System. The lens delivery system consists of an Injector with silicon cushion and a cartridge. Lens Delivery system is a medical device used to implant a **FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC** in a patient's eye.

3.1.1 Device Specifications

Brand/Model – ACRYFOLD-502

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	6.00 mm
Overall Length	12.50 mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	-15.00 D to +53.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It 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.
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 Open 
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
Shelf Life	4 Years

Parameter	Specification
Packing Contains	Mono carton contains (With Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Instruction for use • Patient ID card • Labels Mono carton contains (without Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

Brand/Model – ACRYFOLD-601 & NASPRO-NAS207

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	6.00 mm
Overall Length	12.50 mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	-15.00 D to +53.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It 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.
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	C Loop Closed Hapt 
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
Shelf Life	4 Years
Packing Contains	Mono carton contains (Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Instruction for use • Patient ID card • Labels Mono carton contains (Without Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

Brand/Model – ACRYFOLD-701

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	6.00 mm
Overall Length	11.00
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %

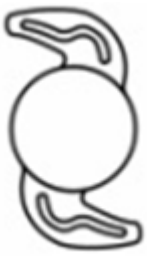
Parameter	Specification
Square Edge	360°
Diopter Range	-15.00 D to +53.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.
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
Shelf Life	4 Years
Packing Contains	Mono carton contains (Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Instruction for use • Patient ID card • Labels Mono carton contains (Without Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

Brand/Model – ACRYFOLD - 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	6.00 mm
Overall Length	11.00 mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	-15.00 D to +53.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It 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.
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
Shelf Life	4 Years
Packing Contains	Mono carton contains (Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector

Parameter	Specification
	• Instruction for use • Patient ID card • Labels Mono carton contains (Without Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

Brand/Model – ACRYFOLD-601Y & NASPRO BBY-NASY207

Parameter	Specification
Optic Type	Monofocal
Optic Material	HEMA – Hydroxyethyl methacrylate (Yellow)
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.46
Optic Design	Biconvex
Haptic Material	HEMA – Hydroxyethyl methacrylate
Optic Diameter	6.00 mm
Overall Length	12.50 mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	-15.00 D to +53.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It 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.
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 

Parameter	Specification
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
Shelf Life	4 Years
Packing Contains	Mono carton contains (Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Instruction for use • Patient ID card • Labels Mono carton contains (Without Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

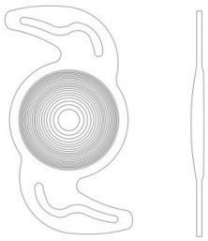
Brand/Model – CM-T Flex- Acryflex-T

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	6.00 mm
Overall Length	13.75 mm
Haptic Angle	10°
"A" Constant	118.0
Water Content	26 %
Diopter Range	-15.00 D to +55.00 D (In steps of 0.5D)
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It is intended to be positioned in the sulcus in the bed of the sclera pocket and covered with a scleral mat by means of a special anchor with a self-locking system, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.

Parameter	Specification
	It is suitable for aphakic eyes, without a capsular bag. its anchoring to the scleral tissue using special anchors without the need for stitches, which simplifies surgery and greatly reduces its duration. It is not placed in the capsular bag. Instead, it is placed in the scleral who do not have an intact capsular bag or have a damaged capsular bag.
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	Anchor Haptic 
Location (One per line) - Capsular bag - Anterior chamber or Posterior chamber - Scleral or Iris or Sulcus Fixated	Scleral
Device Intended User	Ophthalmic surgeon
Patient Population	Adults
Shelf Life	4 Years
Packing Contains	Mono carton contains (Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Instruction for use • Patient ID card • Labels Mono carton contains (Without Disposable Injector System) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

Brand/Model –MULITDIFF-MFD605 & MFDY605

Parameter	Specification
Optic Type	Multifocal
Optic Material	HEMA – Hydroxyethyl methacrylate (Clear and yellow)

Parameter	Specification
Spectra Transmission (Imaging Quality)	Above 85%
Refractive Index	1.46
Optic Design	Biconvex
Haptic Material	HEMA – Hydroxyethyl methacrylate
Optic Diameter	6.00 mm
Overall Length	12.50 mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	0.00 D to +35.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It 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. It provides clear vision at both near and far.
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 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
Shelf Life	4 Years
Packing Contains	Mono carton contains (With Injector) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Instruction for use • Patient ID card • Labels

Parameter	Specification
	Mono carton contains (without Injector) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

Brand/Model –MULITDIFF TRIFIT- MFDY705

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	6.00 mm
Overall Length	11.00 mm
Haptic Angle	0°
"A" Constant	118.0
Water Content	26 %
Square Edge	360°
Diopter Range	0.00 D to +35.00 D in steps of 0.50 D
Diopter Increment	0.50 D
Sterilization	Moist Heat
Intended Use	It 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. It provides clear vision for distance, intermediate and near.
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	Plate Haptic 
Location (One per line)	Capsular bag in posterior chamber

Parameter	Specification
- Capsular bag - Anterior chamber or Posterior chamber - Scleral or Iris or Sulcus Fixated	
Device Intended User	Ophthalmic surgeon
Patient Population	Adults
Shelf Life	4 Years
Packing Contains	Mono carton contains (With Injector) • One Sterile single piece Biconvex Foldable Lens • One Sterile EO Delivery System includes, one Cartridge & Soft Tipped Injector • Instruction for use • Patient ID card • Labels Mono carton contains (without Injector) • One Sterile single piece Biconvex Foldable Lens • Instruction for use • Patient ID card • Labels

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

Intra Ocular Lens functions as a refracting medium to replace the natural lens in the correction of aphakia. The IOL can be placed in Posterior Chamber (ACRYFOLD, NASPRO, NASPRO BBY, MULTIDIFF & MULTIDIFF TRIFIT) & in Scleral (CM-T FLEX). It consists of optic and haptics that are produced from Single material.
Single-piece IOLs tend to be more resistant to damage when used with disposable injector system.

3.1.4 Method of Sterilization

Moist Heat sterilization

3.1.5 Device Lifetime/Stability

The Lifetime of the **FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC** is 15 Years after implantation

3.1.6 Information about the constituents

a. Device with Medicinal Product

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

b. Device with Human or Animal Origin Tissues

Hydrophilic Aphakic Foldable Intraocular 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

Hydrophilic Aphakic Foldable Intraocular 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) or Endocrine-disrupting substances

Hydrophilic Aphakic Foldable Intraocular 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

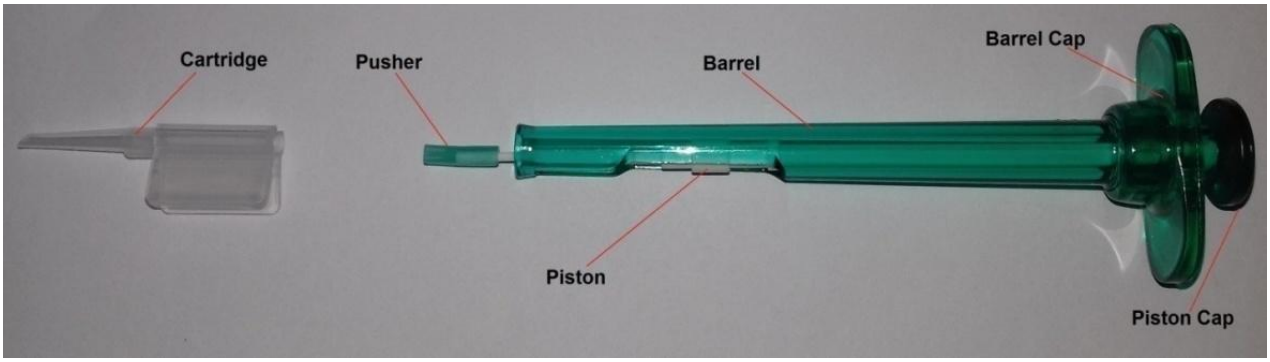
3.2 Reference to previous generation(s) or variants

Legacy Device Name:	Hydrophilic Aphakic Foldable intraocular lens
Brand/Proprietary Name:	Acryfold, Naspro, NasproBBY and Multidiff
Models/Variants:	601, 502, 701, Ultrasmart, 601Y, Nas207, Nasy207, MFD605 and MFDY605
93/42/EEC (MDD) Cert. No.:	10000333391-PA-NA-IND
Notified Body Details:	DNV PRODUCT ASSURANCE AS
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.

3.3 Accessories Details

The lens is supplied with lens delivery system.

Lens Delivery System/Injector:



3.4 Combination with other Medical Devices

FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC is not used with any other medical device. Hence this declaration is not applicable.

4.0 Risks and warnings

4.1 Residual risks and undesirable side effects

Residual Risks

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

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: -

- Temporary Corneal Edema,
- Secondary Cataract Formation,
- Vitreous Herniation into the Formation,
- Mal-positioned Lens,
- Aphakic Glaucoma,
- Temporary Flat Anterior Chamber,
- Retinal Detachment,
- Lens Implants Loop Amputation,

- Endothelial Corneal Dystrophy Anterior Chamber,
- Ocular Infection,
- Pupillary Block,
- Corneal Dystrophy and
- Post operative Posterior capsule opacification (PCO)

4.2 Warnings

- Do Not Resterilize. Resterilization may compromise device performance, which could cause serious harm to the patient's health and safety.
- Do not store intraocular lenses at temperatures below 5 ^{O}C and above 40^{O}C to avoid shocks and fragile.
- Lens should not alter 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 Hydrophilic Aphakic Foldable Intraocular Lens. Hence FSCA or FSN is not applicable.

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

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

No equivalent device has been identified. The clinical evaluation of the Ophthalmic Foldable Hydrophilic Lens 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

#	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.dovepress.com/opacification-of-hydrophilic-intraocular-lenses-after-descemet-strippi-peer-reviewed-fulltext-article-OPTH	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/21879309/	Hydrophilic acrylic intraocular lens optic 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/p	Effect of number and position of intraocular lens

#	Literature #	Source Link	Literature Title
		mc/articles/PMC5859398/	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://www.researchgate.net/publication/6610376_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	Three Hundred sixty-degree barrier effect of a square –edged and an enhanced- edge intraocular lens on centripetal lens epithelial cell migration
17.	L20	https://journals.lww.com/jcrs/Abstract/2015/06000/Glistenings_9_years_after_phacoemulsification_in.12.aspx	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://journals.lww.com/jcrs/Abstract/2007/02000/Clinical_effects_of_primary_posterior_continuous.31.aspx	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://www.changcataract.com/wp-content/uploads/2018/07/ASCRS-White-Paper-Complications-of-Sulcus-Placement-of-Single-Piece-Acrylic-IOLs.pdf	Complications of sulcus placement of single-piece acrylic intraocular lenses
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

#	Literature #	Source Link	Literature Title
24.	L30	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6376833/	Perceived difficulties and complications in learners of phacoemulsification: A principal 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://journaljammr.com/index.php/JAMMR/article/view/345	Effect of Anterior and Posterior Capsular Polishing on the Rate of Posterior Capsule Opacification
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://www.researchgate.net/publication/339681953_CM_T_-_Flex_intraocular_lens_an_innovative_design_for_aphakia_secondary_to_postcataract_surgery	CM T – Flex Intraocular Lens an Innovative Design for Aphakia Secondary to Post cataract Surgery
34.	L41	https://pubmed.ncbi.nlm.nih.gov/32818363/	Innovative intraocular lens design to manage surgical aphakia in an eye with a filtering bleb
35.	L42	https://pubmed.ncbi.nlm.nih.gov/38997613/	Long term surgical results and safety profile of the CM T Flex scleral fixated intraocular lens
36.	L43	https://www.researchgate.net/publication/341845309_Comparison_of_visual_outcomes_after_implantation_of_AtLisa_tri_839_MP_and_Symfony_intraocular_lenses	Comparison of visual outcomes after implantation of AtLisa tri 839 MP and Symfony intraocular lenses
37.	L44	https://pubmed.ncbi.nlm.nih.gov/26292964/	Binocular function to increase visual outcome in patients implanted with a diffractive trifocal intraocular lens

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

5.4 PMCF Clinical Safety & Performance data

Overall, **244** populations were considered for this PMCF study. We clinically investigated all the cases and thoroughly reviewed Clinical Study data. As per the PMCF study, the **FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC** have met the primary and secondary objectives.

The **FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC** – Acryfold, Naspro CM-T Flex, Multidiff & Multidiff Trifit from AI OPTICS (P) LIMITED has reached all the safety and performance requirements with respect to the intended use of the device from the Post Market Follow up Clinical study. The clinical evidence is demonstrated with the relevant Essential Requirements. The Performance and Safety of the device as we claimed it have been established in the Technical Documentation and Instruction for Use (IFU). There were no new risks identified from the PMCF study for the product hence there is 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.

5.5 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.

5.6 Ongoing or planned post-market clinical follow-up

N/A

6.0 Possible diagnostic or Therapeutic Alternatives

- Hydrophobic Acrylic Foldable IOL
- PMMA IOL
- Toric IOL

- Anterior Chamber IOL

7.0 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.

8.0 Reference to any harmonised standards and CS applied

8.1 List of Harmonized Standards

S.No.	Standard	Title	With Injector System	Without Injector System
1	EN ISO 13485: 2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes	A	A
2	EN ISO 14971: 2019/A11:2021	Medical devices - Application of risk management to medical devices	A	A
3	EN ISO 15223-1: 2021/Amd1:2025	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	A	A
4	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	A	NA
5	EN 556-1:2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	A	A
6	EN ISO 10993-10: 2023	Biological evaluation of medical devices. Tests for irritation and skin sensitization	A	A
7	EN ISO 10993-23: 2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	A	A
8	EN ISO 11607-1: 2020+A11+A1:2023	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems	A	A

9	EN ISO 11607-2: 2020/A1:2023	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes	A	A
10	EN ISO 11737-1: 2018/A1: 2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	A	A
11	EN ISO 11737-2: 2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	A	A

List of applicable non-harmonized standards

S.No.	Standard	Title	With Injector System	Without Injector System
1	IEC 62366-1:2015+AMD1:2020	Medical devices — Part 1: Application of usability engineering to medical devices TECHNICAL CORRIGENDUM 1	A	A
2	ISO 2859-1:1999/A1:2011	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	A	A
3	ISO 11979-1: 2018	Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary	A	A
4	ISO 11979-2: 2024	Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods	A	A
5	ISO 11979-3: 2012	Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods	A	A
6	ISO 11979-4: 2008/A1:2012	Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information	A	A
7	ISO 11979-5: 2020	Ophthalmic implants - Intraocular lenses - Part 5: Biocompatibility	A	A
8	ISO 11979-6: 2014	Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability testing	A	A
9	ISO 11979-7: 2024	Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia	A	A

10	ISO 11979-8: 2017	Ophthalmic implants -- Intraocular lenses - Part 8: Fundamental requirements	A	A
11	ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	A	A
12	ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	A	A
13	ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods	A	A
14	ISO 14698-1: 2003	Cleanrooms and associated controlled environments Bio contamination control Part 1: General principles and methods	A	A
15	ISO 14698-2: 2003/Cor 1:2004	Cleanrooms and associated controlled environments Bio contamination control Part 2: Evaluation and interpretation of Bio contamination data	A	A
16	ISO 17665:2024	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	A	A
17	ISO 11737-3: 2023	Sterilization of health care products - Microbiological methods-Part 3: Bacterial endotoxin testing	A	A
18	ISO 11140-1: 2014	Sterilization of health care products - Chemical indicators -- Part 1: General requirements	A	A
19	ISO 11140-3: 2007/Cor 1:2007	Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	A	A
20	ISO 11138-1: 2017	Sterilization of health care products - Biological indicators - Part 1: General requirements	A	A
21	ISO 11138-2: 2017	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes	A	NA
22	ISO 11138-3: 2017	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for Moist heat sterilization processes	A	A

23	ISO 10993-1:2018	Biological evaluation of medical devices. Evaluation and testing within a risk management process	A	A
24	ISO 10993-3: 2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	A	A
25	ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	A	A
26	ISO 10993-6: 2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	A	A
27	ISO 10993-7: 2008/Amd 1:2019	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	A	NA
28	ISO 10993-11: 2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	A	A
29	ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	A	A
30	ISO 10993-18: 2020/A1:2022	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	A	A
31	ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer	A	A
32	ISO TR 20416: 2020	Medical devices - post-market surveillance for manufacturers	A	A
33	ISO 14155: 2020	Clinical investigation of medical devices for human subjects - Good clinical practice	A	A
34	ISO/TR 24971: 2020	Medical devices-Guidance on the application of ISO 14971	A	A
35	ISO 2859-1: 1999/A1:2001	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	A	A
36	IEC 62366-1: 2015/AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices TECHNICAL CORRIGENDUM 1	A	A
37	USP <85>	Bacterial Endotoxin Test (BET)	A	A
38	ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	A	A

39	ASTM D4169 - 16	Standard Practice for Performance Testing of Shipping Containers and Systems	A	A
40	ASTM D4332-14	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	A	A
41	USP 37 NF 32:2014	United States of Pharmacopeia/ National Formulary official, December 1, 2014, to April 30, 2015	A	A
42	BP 2013	British Pharmacopeia 7th edition, Version 17	A	A
43	ICH Q1A (R2) 2003	International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use. Stability testing of New Drug substances and products Q1A (R2) Version 4, Feb 2003.	A	A

9.0 Revision history

SSCP Rev. No.	Date Issued	Change description	Rev. Validated by the NB
01	01.11.2023	Initial release- EU MDR 2017/745 regulations update	☐ Yes Validation language: English ■ No
02	01.11.2024	As per annual review update 2023-24	☐ Yes Validation language: English ■ No
03	10.11.2025	The two models given in the QRF is added in the TD File-Monofocal (CM-T FLEX) & multifocal (MFDY705) as per Initial Assessment-Technical Dated 17.10.2025 & Annual review update 2024-25	☐ Yes Validation language: English ☐ No