CE 2460

MULTIFOCAL HYDROPHILIC ACRYLIC FOLDABLE IOL

An ISO13485 certified company

INSTRUCTION FOR USE

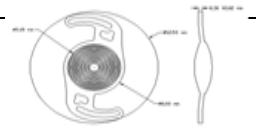
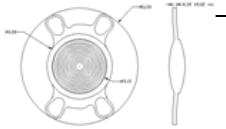
I. INTENDED USE OF THE IOL:

Multifocal Hydrophilic Acrylic Foldable OL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. Hydrophilic multifocal IOL is based on the principle of diffraction, whereby light slows down and changes direction when it encounters an obstacle and gets directed towards distant, intermediate and near focal points.

II. DEVICE DETAILS:

Implantable Lifetime: -15 years

All our lenses are compatible for all our lens delivery system models covered under brand name "Aquaject Plus", "LDS" & "X-Ject". Lens Delivery System also can come in Single pack depending upon Surgeon's requirement.

Model Number	Loop	Optic Size	Overall Size	Material	Diopter Range	Optic Design	Haptic Angulation	Color	Picture
YSQFL600DF/HFL2125605NYD	Flex loop	6.00	12.50	Hydrophilic 25%	(+) 8 to (+) 32 D	Bifocal	5°	Yellow	
YSQQ600DF/M AY4	Quadra	6.00	11.00	Hydrophilic 25%	(+) 8 to (+) 32 D	Bifocal	5°	Yellow	

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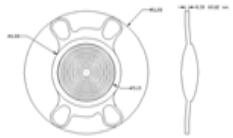
Model Number	Loop	Optic Size	Overall Size	Material	Diopter Range	Optic Design	Haptic Angulation	Color	Picture
PBFY37MF/HQL1110605NYD	Quadra	6.00	11.00	Hydrophilic 25%	(+) 8 to (+) 32 D	Trifocal	0°	Yellow	

Doc No-1110

Effective Date: 01/08/2025

Issue: 03

Rev: 07

III. DEVICE DESCRIPTION:

Hydrophilic multifocal IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. Hydrophilic multifocal IOL is based on the principle of diffraction, whereby light slows down and changes direction when it encounters an obstacle and gets directed towards distant, intermediate and near focal points. The IOL is capable of being folded prior to insertion, and takes its original unfolded shape after implantation.

The IOLs are manufactured from an advanced Polymer of Hydrophilic Acrylic material, UV blocker.

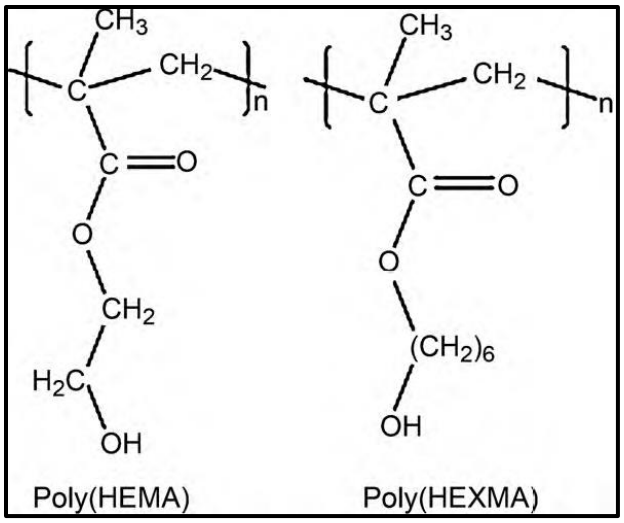
The hydrophilic acrylic polymer has inbuilt property to absorb ultraviolet radiation with transmission of <10% of light of wavelength 360 nm or lower which ensures protection of the eye from UV radiation.

IV. DEVICE MATERIAL DESCRIPTION:

Multifocal Hydrophilic Acrylic Foldable IOL devices are made of a network of hydrophilic chains that are able to absorb water, thus also called as hydrogels. Because of their water-absorbing capacity, they are well-suited for long-term application in an aqueous environment1.

The polyacrylic network is prepared by free-radical co-polymerization of a hydrophilic monomer, 2-hydroxyethyl methacrylate (HEMA) and 6-hydroxyhexyl methacrylate (HEXMA) with a cross-linking agent (ethylene glycol dimethacrylate(EGDMA), for instance)1.

In the dry state, these materials are rigid and unfoldable. However, upon immersion in water, they become flexible and soft resulting in a hydrogel. Normally, the equilibrium water content of the hydrophilic acrylic IOLs is in the range of 18–38 wt%1.



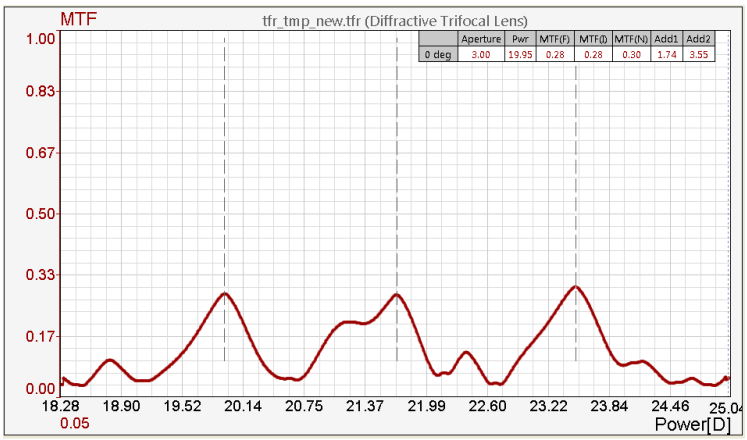
Chemical structures – Poly (HEMA) and Poly (HEXMA)

V. DEVICE TECHNICAL SPECIFICATIONS:

- Dioptric Power: (+) 8 to (+) 32 D
- Aspherical power range: -5 to 42 (1.00 to 30.00 with 0.5 increments)
- Additional Value: 1.75, 3.0, 3.5
- MTF value: ≥ 0.43
- Optic Resolution: ≥ 70%
- Optic diameter: 5.0mm – 7.0mm(0.25 Increments)
- Overall diameter / length: 11mm – 13.50 mm (0.50 Increments)
- Haptic Angle: 0^{o} – 10^{o}
- Optic material: Hydrophilic Acrylic with 25% water content
- Optic design: Diffractive multifocal, Bifocal, Trifocal with aspheric surface
- Configuration: Bi-convex
- Color: Yellow
- Haptic configuration: Quadra, Flex loop
- Ref. Index: 1.45-1.50

MTF GRAPH:

Modulation Transfer Function (Fig. 1)



VI. MEDICAL INDICATION:

Hydrophilic- Multifocal intraocular lens is indicated for the replacement of human crystalline lens to achieve visual correction of aphakia in patients when extracapsular cataract extraction or phacoemulsification is performed. The hydrophilic multifocal lens is intended for placement in the capsular bag. In patients with the need for near, distant and/or intermediate vision.

VII. MODE OF ACTION:

When implanted in the posterior chamber of the eye, the IOL is intended to replace the natural crystalline lens and function as a refracting medium in the correction of aphakia. For trifocal the anterior optic contains an additional power of 3.5 Diopter to support Near vision and 1.75 Diopter for intermediate vision. For bifocal the anterior optic contains an additional power of 3.0 Diopter to support Near vision.

VIII. INTENDED USER:

Ophthalmic surgeons only.

IX. TARGET POPULATION:

Aphakic adult patients of age 18 years and above.

X. CALCULATION OF IOL POWER:

It is recommended that the surgeon use a power calculation method in which he is most familiar and comfortable with. In general, the power of the IOL for each patient can be estimated from prior

refractive error or calculated from the corneal radius, depth of the anterior chamber and axial length of the eye according to formulas in corresponding literature.

XI. A CONSTANT INFORMATION:

The A constant listed on the outer label is presented as a guideline and is a starting point for implant power calculation. It is recommended that surgeon calculates their own personalized A constant based on clinical experience with the particular IOL models, surgical techniques, measuring equipments and post-operative results.

XII. METHOD OF STERILIZATION:

Intraocular lens is steam sterilized in a Glass vial or small blister or preloaded Blister contained within a sealed sterilizable pouch. The contents of the pouch/vial/blister are sterile unless the package is damaged or opened.

XIII. CLINICAL BENEFIT OF MULTIFOCALHYDROPHILIC ACRYLICFOLDABLE IOL:

Compared to regular intraocular lenses (IOL), multifocal IOLs can help you see near distances and reduce the need for glasses or “readers”.

Hydrophilic multifocal IOL helps in correcting near, intermediate and distance vision and reduce the need for glasses or readers.

XIV. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:

Link for the availability to SSCP: Link to be provided after notified body acceptance of SSCP.

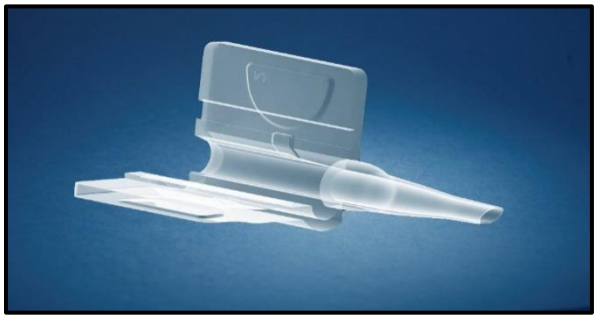
XV. CONDITIONS OF STORAGE & TRANSPORT:

Store & transport hydrophilic multifocal IOL between 5^{o}C to 40^{o} C. and Keep away from sunlight.

XVI. RECOMMENDATION FOR CHOOSING LENS DELIVERY SYSTEM:

The use of a lens delivery system is essential for the implantation of the intraocular lens. It consists of a cartridge, injector, and cushion.

All Multifocal Hydrophilic IOL is supplied in single/Regular pack. Lens Delivery System also can come in Single pack depending upon Surgeon's requirement.



Cartridge

Injector

MULTIFOCAL HYDROPHILIC ACRYLIC FOLDABLE IOL

Model Number	Loop	Compatible LDS model	
		Dipoter Range(+) 8 to (+)24.5D	Dipoter Range(+) 25 to (+)32D
YSQFL600DF/HFL2125605NYD	Flex loop	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
YSQQ600DF/M AY4	Quadra	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
PBFY37MF/HQL1110605NYD	Quadra	AQ-S-B-MJ22,	AQ-S-B-MJ22,

MULTIFOCAL HYDROPHILIC ACRYLIC FOLDABLE IOL

Model Number	Loop	Compatible LDS model	
		Dipoter Range(+) 8 to (+)24.5D	Dipoter Range(+) 25 to (+)32D
		AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide

XVII. INSTRUCTION FOR THE REMOVAL OF IOL FROM CONTAINER:

- Remove IOL vial from peelable pouch. Check the presence of liquid in the vial. Firmly hold vial in one hand and unscrew the cap with your fingers. Remove the rubber stopper and remove the IOL from the vial.
- In case vial is having Holder device then take out the Holder on which IOL is mounted, open the Holder carefully and take out the IOL.

- In case vial is having Holder Folder device then take out the Holder Folder on which IOL is mounted and fold the IOL with the device.
- If IOL packed in Blister, remove IOL blister from peelable pouch, firmly hold blister in one hand and pull the aluminium lid carefully and take out the IOL.
- In case Blister is having Holder device then take out the Holder on which IOL is mounted, open the Holder carefully and take out the IOL.
- In case of IOL packed in preloaded Blister, a leaflet containing diagrammatic representation for handling of preloaded Blister has been provided separately.
- Exercise caution when removing the IOL as the IOL can be easily damaged. Inspect IOL for debris and damage. The IOL should be handled by the haptic portion only.

XVIII. INSTRUCTION FOR USE:

In order to avoid temporary opaqueness at the time of implantation of the only current method recommended is to equilibrate the IOL at 25^0 C prior to implantation for a minimum of 60 minutes.

Preparatory Steps

- Prior to the implant, examine the IOL package for IOL size, Spherical Power, Cylinder Power, Axis of the IOL, expiration date and other specifications.
- Check the integrity of the sterile packaging before use.
- Do not use if packaging integrity is found compromised.
- The IOL must be opened in a sterile environment and used as soon as possible after opening the box.
- After opening, verify primary package information (e.g., model, power, serial number) is consistent with the information on the outer package labeling.
- Open the blister or screw cap or rubber stopper & take out the lens in a sterile environment.
- Pick the lens haptic gently with the help of forceps while ensuring that no optic part is in contact with the forceps.
- Examine the lens optics as well as haptics part to ensure that no dust or particles have attached to it, and examine the lens optical surface for other defects.
- Soak & Rinse the IOL with a sterile balanced salt solution until ready for implantation.

- Grasp the IOL by the haptic and rinse in a balanced saline solution prior to implantation into the eye. Use the IOL immediately. Do not leave the IOL exposed to air for too long as it will dehydrate.
- It is imperative that the IOL be placed in the capsular bag and highly recommended that an extra capsular cataract extraction/Phacoemulsification procedure be used.

Before Surgery	After Surgery
If you take medicine for your heart, blood pressure, or asthma, you may take your medicine with a sip of water in the morning of your surgery. If you have diabetes, please check with your doctor about whether to take your medicine before surgery.	Your eye may feel like it has grit or sand in it after the operation. Your eye may itch and be more sensitive to light. These feelings are normal and should gradually get better in the days after surgery. Do not rub, scratch, or press on your eye.
Do not eat or drink anything after midnight the night before surgery.	Redness is normal for the first few days. This should get better in three to four days after surgery.
Bring your medicine that you are taking with you in the morning of surgery.	If you are suggested to wear an eye shield, use it as directed by your doctor. Do not remove it until they say.
Your doctor may prescribe some eye drops for several days before the surgery. Follow the instructions on how to use them.	You may want to wear glasses during the daytime hours to prevent anything from touching your eye and to remind you not to touch it.
Lab tests may be done before your surgery. Your doctor will suggest the tests needed.	You may want to wear sunglasses when outside. The operative eye may be more sensitive to sunlight which can cause pain.
Wash your hair and face the morning of the surgery.	Your doctor may ask you to use eye drops to help healing and decrease the risk of infection. Ask your doctor about how to use your eye drops and use it as in the prescription.
You can brush your teeth that morning, but do not swallow any water.	Avoid smoke, dust, and aerosol spray. And try not to bend from the waist to pick up objects on the floor. Do not lift any heavy objects. You can walk, climb stairs, and do light household chores.
Do not wear makeup, jewelry, nail polish, lotions, or perfumes and wear comfortable clothes.	It will not harm your eyes to read or watch TV.
You must have a responsible adult to drive you home after your surgery.	Always wash your hands before using eye drops or having your hands near your eyes for any reason.
	You may return to normal activities when your doctor allows. Ask your doctor when you can resume driving.

OPERATIVE PROTOCOL

The protocol of implantation is the responsibility of the surgeon. He must decide the procedure which is the most adequate based on the techniques which are most current and best executed on his own experience.

DISPOSAL

Discarded IOLs (used or unused) are classified as medical (clinical) waste that harbors a potential infection or microbial hazard and must be disposed of accordingly

XVIII. CONTENTS OF BOX:

The packaging contains sterile product, instruction for use, patient implant card, patient card label, Informative instructions leaflet, Patient Information Leaflet and peelable labels. The peelable labels display the Device name, Serial number, Lot No., IOL diopter, model number, UDI. These labels are designed to be affixed to the patients hospital chart and the physicians chart. One of these labels should be affixed to the patient's identification card contained in the IOL box and given to the patient as a permanent record of their implant.

XIX. CONTRAINDICATIONS:

Surgeons should explore the use of alternative method of aphakia correction and consider IOL implantation only if alternatives are deemed unsatisfactory to meet the needs of the patient.

Implantation is not advisable with the diagnosis or the treatment of pathology, or presents a risk to the sight of the patient. These conditions are (non-exhaustive list):

- Choroidal hemorrhage
- Chronic severe uveitis
- Excessive vitreous loss
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma & Excessive vitreous pressure
- Microphthalmos
- Aniridia
- Posterior capsular rupture &Zonular separation (preventing fixation of IOL)

- Proliferative diabetic retinopathy (severe)
- Severe corneal dystrophy & optic atrophy
- Rubeosisiridis-Congenital bilateral cataract, recurrent anterior or posterior segment inflammation of unknown etiology, Rubella cataract
- Retinal detachment
- Iris atrophy
- Severe ametropia and aniseikonia
- IOL replacement or extraction
- Excessive intraoperative vitreous loss
- Hemorrhage

In above condition, IOL implantation can be done with judgement of Surgeon.

XX. COMPLICATIONS AND ADVERSE EVENTS:

As with any surgical procedure, there is risk involved. The possible adverse effects and complications accompanying a cataract surgery may be the following (non-exhaustive list):

- Posterior capsule opacification
- Cystoid Macular edema
- Corneal edema
- Pupillary block
- Iridocyclitis
- Hyalites
- Endophthalmia and Panophthalmia
- Iritis
- Recurrent anterior or posterior segment inflammation of unknown etiology
- IOL precipitates
- IOL Decentration
- IOL dislocation and subluxation
- TASS (Toxic anterior segment syndrome)
- There may be short-term interferences with diagnostic tools such as optical torch or MRI; risks related to this have been captured in risk management and residual risks are

acceptable because of the low probability of occurrence of harm. The user is informed about such risks via IFU.

- Adverse reactions (hypopyon, Intraocular infection, acute corneal decompensation and/or secondary surgical intervention) and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were previously expected in nature, severity or degree of incidence shall be reported to the manufacturer (OMNI Lens Pvt Ltd) and the competent authority of the Member State in which the user and/or patient is established.

I. ADVERSE EVENTS REPORTED FROM CLINICAL STUDY:

- raised IOP,
- redness of the eye,
- eye pain,
- corneal stromaoedema
- cystoid macular oedema

II. RESIDUAL RISKS

The finished device is having the Residual Risks such as

- IOL Dislocation,
- Allergic Reaction,
- Undesired vision correction,
- Inconvenience to patient,
- Environmental Contamination.

XXI. WARNINGS & PRECAUTIONS:

- Do not re-sterilize Intraocular Lens by any methods. If re-sterilized, the lens may lose its functionality and may lead to infection.
- Use only sterile intraocular irrigating solution to rinse and/or soak IOLs to retain sterile condition and avoid contamination.
- Once packaging has been opened, the intraocular lens must be used immediately. The IOLs of Hydrophilic nature can cause the IOL to absorb substances with which it comes into contact, such as, disinfectants, medicines, blood cells, etc. This may cause a “Toxic IOL Syndrome”. Rinse the IOL carefully before implantations with sterile balance salt solution or balanced saline solution.
- Do not re-use the IOL If IOL is reused, it can cause loss of vision/serious complication.

- Do not use the intraocular lens after the expiration date shown on the outside package label. After expiry, sterility is not retained and can cause infection.
- Handle the intraocular lens carefully. Rough handling or excessive handling may damage the IOL. Handle the lens by haptic
- A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and /or assisted in numerous surgical implantations and successfully completed one or more courses on intraocular lenses prior to attempting to implant IOLs.
- The surgeon must be aware of the risk of opacification of the intraocular lens, which may necessitate IOL removal.
- All cases of IOL removal must be reported to Omni Lens.
- In case of any adverse event noted, contact manufacturer (Omni Lens Pvt. Ltd.) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs. A report describing the adverse event, therapy adopted, traceability detail of the lens used will be requested.
- Omni will not be responsible for any damage that may occur to a patient due to not following above listed warnings. The risks associated are: decentration of IOL, contamination, infection or loss of vision in operated eye.
- In order to successfully implant intraocular lens, choose right lens delivery system.

For the Multifocal intra ocular lenses additional warnings are:

- The Physician should consider the following points that are unique to the Multifocal/Tri focal IOL.
- It is recommended emmetropia be targeted for optimum visual performance.
- Patients with significant preoperative astigmatism or expected to get postoperative astigmatism > 1.0 D may not achieve optimal visual outcomes.
- Care should be taken to achieve Multifocal/Tri focal centration, as lens decentration may result in a patient experiencing decrease of visual quality under certain lighting conditions.
- As it is the case for all Multifocal/Tri Focal IOLs with simultaneous vision, some patients may experience a reduction of contrast sensitivity compared to monofocal lens (IOL) that may be more important in low lighting conditions.

- Some patients may experience some visual effects due to the superposition of focused and unfocused multiple images at different foci. These visual effects may be perceptions of halos and radial lines around point source of light under night time conditions.

IOL is void of all warranties expressed or implied if

- IOL is re sterilized by anyone.
- IOL is repackaged by anyone.
- IOL is altered in any manner.

PATIENT INFORMATION

The expected device lifetime is 15 years. The surgeon performing the implantation must inform the patient about the implant and all known side effects and risks. The patient should be instructed to properly inform the doctor in charge about any side-effects after implantation. In case of any serious incident the manufacturer has to be immediately informed

XXII. EXPIRATION DATE INFORMATION:

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should not be used.

XXIII. RETURN GOODS POLICY:

Omni Lens Pvt. Ltd. accepts returned IOLs for exchanges only in case of manufacturing defect. No cash refunds will be issued. To return IOLs, you must first obtain a Return authorization number from customer services department. No returned goods will be accepted without proper authorization number. Returned IOLs should be shipped by traceable method. No credit will be given to lost or damaged IOLs in shipment. IOLs will be replaced as long as they are returned within six months of their original invoice date.

XXIV. DISPOSE OF USED MEDICAL DEVICE CONTAINER/PACKAGE:

- Do not dispose damaged or explanted device or its packing with household trash. Disposal of devices and its packaging is considered a biohazard. Follow local regulatory guidelines for disposing off devices and its packaging safely.

- Put used device package in disposal container as per your community guidelines for the right way to dispose of your disposal container.
- You may use a household container that is: made of a heavy-duty plastic, can be closed with a tight-fitting, puncture-proof lid, without sharps being able to come out, upright and stable during use, leak resistant, properly labeled to warn of hazardous waste inside the container.
- When your disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your disposal container. There may be state or local laws about how you should throw away used device package.
- Do not recycle your used sharps disposal container.

EU REP Obelis S.A. Boulevard General Wahis 53 1030, Brussels, Belgium Tel: +3227325954 Fax: +3227326003 Email: mail@obelis.net	 Omni Lens Pvt. Ltd. A-69/A-70, Electronic Estate, GIDC, Sector-25, Gandhinagar- 382016, Gujarat, India. **Reg. office:** 5, Samruddhi, Opp. Sakar III, Navarangpura, Ahmedabad- 380014, Gujarat, India. Email: info@omnilens.in Website: www.omnilens.in
 Do Not Use If Package Is Damaged or unintentionally opened before use	 Do Not re-use
 Do not resterilize	 Keep away from sunlight
 Consult Instructions For Use	 Keep dry
 Medical Device	 Single sterile barrier system with protective packaging inside

MULTIFOCAL HYDROPHILIC ACRYLIC FOLDABLE IOL

EU REP Authorized Representative in the European Union	STERILE Sterilized using steam
 Storage Condition between 5°C to 40°C	 Manufacturer
 Date of manufacture	 Expiry Date
LOT Sterile Batch No.	UDI Unique device identifier
SN Serial number	# Model number