

MEDICONTUR OPHTHALMIC MEDICAL DEVICES

Patient Information Leaflet



MEDICONTUR

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1. Introduction

This leaflet helps you understand cataracts and other vision problems, such as presbyopia or refractive errors. Since cataract cannot be cured with medication or glasses, the only effective solution is a routine procedure to replace the eye's natural lens with an Intraocular Lens (IOL). This safe treatment can restore clear vision and significantly reduce your dependence on spectacles. The following pages explain the surgical process and the range of innovative Medicontur Ltd. lenses designed to improve your quality of sight.

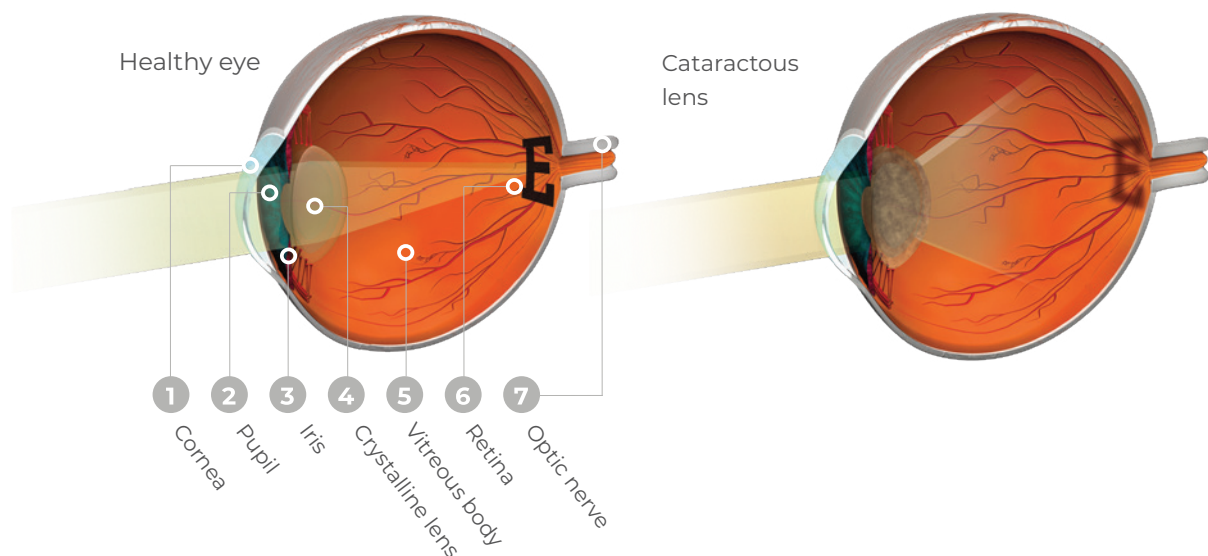
2. Common vision problems

Vision is a key part of our everyday life because it helps us understand the world around us. Eye problems — such as nearsightedness, farsightedness, astigmatism, presbyopia (age-related difficulty seeing up close), and cataracts — can reduce the quality of our vision and, as a result, affect our overall quality of life.

When light enters the eye, it passes through several parts before reaching the retina, where a clear image is formed. The natural lens of the eye focuses the light by bending the rays so they meet at a single point on the retina.

2.1 What is cataract? How does it affect vision?

A cataract happens when the natural lens becomes cloudy instead of clear. This blocks light and makes vision blurry. Cataract usually develop with age, especially after 50, but they can also be caused by injury, certain medications, or diseases. Cataract can affect one or both eyes. The only effective way to treat a cataract and restore vision is through surgery to replace the cloudy natural lens with an artificial one.



2.2 What is presbyopia?

Presbyopia is a condition of the eye where the natural crystalline lens has lost its flexibility and adaptability, making it increasingly difficult for the eye to focus on nearby objects.

2.3 What is a refractive error?

Refractive error occurs when the eye does not bend light properly, causing blurred vision. The main types are myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. In a healthy eye, the cornea is round, so light focuses at one point on the retina, creating a clear image. With astigmatism, the cornea is unevenly shaped, so light does not focus at a single point, leading to blurred vision.

2.4 What is Macular Degeneration?

Macular degeneration is a group of diseases affecting the back of the eye responsible for sharp central vision. You need this area for reading, driving, and recognizing faces. Types include age-related, diabetic, and myopic macular degeneration. The most common form is age-related macular degeneration (AMD), especially in people over 55.

AMD is a condition where the retina gradually deteriorates, leading to loss of central vision. It can involve deposits (drusen), damage to retinal cells, or abnormal blood vessel growth. As it progresses, symptoms may include blurred or distorted straight lines, dark or empty spots in the center of vision, and in rare cases, changes in color perception.

3. What solutions can we offer?

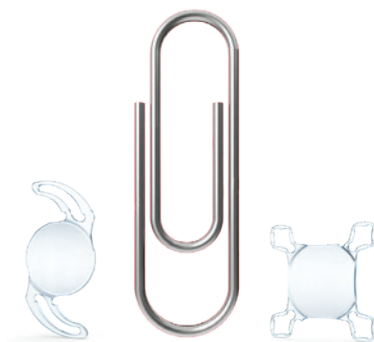
3.1 What is a capsular Intraocular Lens (IOL)?

Intraocular lenses are artificial lenses used in cataract surgery and/or refractive correction to correct visual problems.

They replace the cloudy crystalline lens of the eye to restore vision. IOLs are implanted in the capsular bag that originally wraps around the natural crystalline lens. Medicontur intraocular lenses are intended for adult patients (18 years old and older) diagnosed with a cataract and/or ametropia (hyperopia, myopia, astigmatism) and/or presbyopia.

Medicontur offers different types of intraocular lenses (monofocal, trifocal, EDoF) to best suit the patient's needs. The soft and foldable intraocular lenses are made from a transparent biocompatible hydrophilic or hydrophobic material, with a built-in UV blocker. Yellow IOLs have a yellow chromophore for filtering harmful blue light. The lifetime of the IOLs is defined as 20 years – at least – from the implantation. During this period of time, the characteristics and performance of the device do not adversely affect the health or safety of the patient when the device is subjected to the stresses which can occur during normal conditions of use. These intraocular lenses are neither visible nor perceivable in the eye.

The actual size of the IOL: compared to a standard paper clip (28 mm):



3.2 1stQ AddOn® IOLs

The 1stQ AddOn® Intraocular Lens is a specialized supplementary lens designed for patients who have already undergone cataract surgery and have a primary IOL implanted, but wish to further refine their vision. This lens is implanted into the ciliary sulcus, positioned discreetly behind the iris and in front of the primary lens already in the eye. Its main purpose is to “fine-tune” your sight by correcting occasionally remaining refractive errors such as nearsightedness, farsightedness, or astigmatism, while also addressing presbyopia to improve near and intermediate vision. Made from a hydrophilic acrylic material with a built-in UV blocker, the 1stQ AddOn® lens acts as a precision tool to help you reach the ultimate goal of a spectacle-free life.

3.3 Capsular Tension Ring

The Medicontur Capsular Tension Ring (CTR) is a small, flexible ring implanted into the natural lens capsule during cataract surgery. It is designed to stay permanently in the eye and helps stabilize and support the capsule when the eye’s supporting structures are weak or damaged. By improving the stability of the capsule, the CTR can help reduce surgical complications, support proper positioning of the intraocular lens, and lower the risk of capsule shrinkage or clouding after surgery.

Your doctor will decide whether implantation of a CTR is necessary or expected to provide additional benefit during your surgery. CTR stabilize the capsular bag in cases of high myopia or specific conditions involving zonular weakness, such as pseudoexfoliation and Marfan syndrome.

4. IOL optics and their performances

A variety of intraocular lenses available on the market have different optical design and performance.

4.1 Monofocal intraocular lenses

Monofocal intraocular lenses are the most widely used IOLs. They provide sharp vision at only one distance. Clear vision is typically set for far distance, and glasses are needed for intermediate and near vision tasks. Patients with corneal astigmatism can be implanted with a **monofocal toric IOL**.

4.2 Trifocal intraocular lenses

Trifocal intraocular lenses are an advanced option for the correction of presbyopia and can significantly reduce the need for glasses after cataract surgery or refractive lens exchange. They provide functional vision at near, intermediate, and far distances simultaneously. In patients with corneal astigmatism, **trifocal toric IOLs** can also be used to reduce or eliminate astigmatism.

Trifocal intraocular lenses offer a high level of spectacle independence; however, compared to monofocal IOLs, some side effects might appear due to the trifocal technology that splits the entering light. Besides reduced contrast sensitivity, patients might experience light phenomena (dysphotopsia), halos, and glares, when looking into a bright light source in a dark environment.

Trifocal intraocular lenses might not be suitable for patients suffering from eye diseases, such as glaucoma, diabetic retinopathy, diabetic macular oedema, or macular degeneration. In the presence of any existing medical condition, it is the responsibility of the treating physician to determine the most appropriate type of intraocular lens to be implanted.

4.3 Extended Depth of Focus (EDoF) intraocular lenses

Extended Depth of Focus (EDoF) intraocular lenses provide sharp vision from far to intermediate distances (such as a computer screen or a car dashboard). EDoF intraocular lenses ensure more spectacle independence than monofocal IOLs, patients are usually spectacle independent for far and intermediate distances, but they might need reading glasses for close-up activities such as reading and doing precision work. The main advantage of EDoF lenses is that compared to trifocal IOLs, they are usually less associated with disturbing light phenomena (dysphotopsia) that are typically perceived while looking into bright light sources in a dark environment. Patients with corneal astigmatism can be implanted with an **EDoF toric IOL** to reduce or eliminate the level of astigmatism at the same time.

4.4 Scharioth Macula Lens (SML)

SML is a bifocal 1stQ AddOn® IOL with a specifically designed central optic area providing high addition power of +10.0 diopter, developed by Prof. Gabor B. Scharioth. SML is intended for monocular implantation in the better-seeing eye of patients suffering from dry AMD (Age-related Macular Degeneration), without affecting distance vision or visual field. By magnifying the image twofold, SML directs light rays to the rest of the damaged foveal region, thus enabling the patient to read, write, and resume hobbies they had to stop due to vision problems.

5. Eye lens replacement procedures

5.1. Cataract surgery

Cataract surgery is a safe and common procedure to remove the cloudy lens of an eye and replace it with an artificial lens. This is a safe and rapid procedure, with a success rate over 98% that typically takes only 15 to 30 minutes per eye. Depending on the patient's needs, it can be performed on both eyes during a single session or scheduled one eye at a time.

Before the operation, precise measurements are taken to determine the correct power for your new lens. During the painless procedure, the eye is numbed with drops and a tiny incision is made to remove the cloudy lens and replace it with a clear artificial one. The incision is so small that it usually heals on its own without stitches, and a protective patch is applied to the eye for the initial recovery period.

After the surgery, it is essential to use your prescribed eye drops and avoid heavy lifting or strenuous activities while the eye heals.

While complications are very rare and usually treatable, you should contact your doctor immediately if you experience any issues, such as severe or worsening pain, a sudden decrease in vision, increased redness, discharge, or the appearance of new flashes of light or floaters. You will receive an official **Implant Card** containing all the specific details about your new lens and the procedure.

5.2 Capsular Tension Ring

During cataract surgery, a capsular tension ring (CTR) may be used if the natural lens capsule is weak or not fully stable. After the cloudy lens has been removed, the ring is placed into the now empty capsular bag. It gently supports the capsule and helps it keep its circular shape, making it easier for the surgeon to position the artificial lens securely centered. This added stability can help make the procedure safer and reduce the risk of complications.

5.3. Refractive lens exchange

This procedure and cataract surgery are essentially the same procedure. While the cataract surgery aims to restore vision by removing the blurred crystalline lens in the capsular bag and replacing it with an artificial one, the purpose of refractive lens exchange is to reduce spectacle dependence of presbyopic patients by replacing the rigid crystalline lens with a multifocal IOL.

5.4 1stQ AddOn® implantation

If your vision isn't perfect after cataract surgery, an 1stQ AddOn® secondary lens can fine-tune your sight and help eliminate the need for glasses. This small lens is safely placed in a natural space called the ciliary sulcus, right in front of the original artificial lens in the capsular bag. A key benefit of this procedure is that it is reversible, allowing the lens to be removed if needed.

The procedure is quick, painless, and performed using numbing eye drops. Through a small, self-sealing incision that requires no stitches, the surgeon gently inserts the lens using a specialized injector. The eye is kept hydrated and protected throughout the process, and the surgery concludes with a protective patch to ensure safe healing.

5.5 SML implantation

The SML (Scharioth Macula Lens) surgery is performed in the same manner as the 1stQ AddOn® procedure, and the following recovery steps are required during the following few weeks after the operation:

- Patients need to practice performing near vision reading tasks without the use of magnifying aids.
- This should be performed 2-3 times a day for at least 20 minutes at a time during the first 4-8 weeks post SML implantation.
- The eye without the SML implantation may need to be covered during reading for the first few days after SML implantation.
- The reading material needs to be held at approximately 15 cm from the patients' face.
- Good lightening and high contrast reading material are recommended.

6. Post-Surgery Instructions

After your surgery, it is essential to follow your doctor's instructions carefully to ensure a smooth recovery. You will likely return home the same day and should attend all scheduled follow-up visits, starting as early as the next day.

Key points for your recovery include:

- **Medication:** Apply all prescribed eye drops and take your medications exactly as instructed to prevent infection and speed up healing.
- **Protection:** Avoid any activities that could strain or harm your eye. Be especially cautious when driving at night or in low light, as you may experience temporary visual disturbances like halos or starbursts while you adjust to your new lens.
- **Self-Assessment:** It typically takes 4 to 6 weeks for your vision to fully stabilize. During this time, monitor your progress and contact your healthcare team immediately if you experience persistent pain, redness, or a sudden decline in vision.
- **Patience:** Most patients see better within a week or two, but it is normal to need some time to get used to your new intraocular lens. Always consult your doctor if you have any questions or concerns.

7. Complications, warnings, and precautions

7.1 Complications of cataract surgery

While cataract surgery is a routine procedure, it does involve certain risks and potential complications that you should discuss with your doctor. These may include general surgical issues such as infection, inflammation, bleeding, or reactions to medication, as well as eye-specific symptoms like redness, light sensitivity, or increased eye pressure. In rare cases, the back or front of the eye may experience swelling, or the new lens may not sit in the perfect position, which could affect your vision or require a follow-up procedure to correct. Although these occurrences are uncommon and usually treatable, there is a very small chance that your vision could worsen after the operation, so it is important to consult your ophthalmologist about any unexpected changes or concerns.

Undesirable complications may occur during or following cataract surgery:

- **Corneal damage or edema:** Swelling of the cornea (the clear front surface of the eye).
- **Secondary glaucoma:** Increased pressure inside the eye due to a specific cause.
- **Intraocular infection:** Infection occurring inside the eye.
- **Asthenopic discomfort:** Eye strain and difficulties adapting to the new lens.

- **Uveitis or Persistent iritis:** Inflammation of the eye's internal structures or the colored part (iris), which can cause redness, pain, and blurred vision.
- **Cystoid macular edema:** Painless swelling of the retina, affecting central vision.
- **Zonule or capsule damage:** Damage to the structures holding the lens, which can lead to IOL dislocation or impaired function.
- **Posterior capsule opacification (PCO):** A cloudy layer of scar tissue forming behind the new lens implant.
- **Luxation:** Displacement of the lens, leading to double vision, glare, or shadows.
- **Macular degeneration:** Long-term damage where leaking blood vessels affect central vision, potentially leading to blindness over several years.
- **TASS or Endophthalmitis:** Severe inflammation or infection of the eye's interior cavity.
- **Retinal tear, break, or detachment:** Serious conditions where the light-sensitive layer at the back of the eye pulls away.
- **Ptosis:** Drooping of the upper eyelid.
- **Light sensitivity:** Increased discomfort in bright light.
- **Diplopia:** Double vision.
- **Visual disturbances (Dysphotopsias):** Seeing halos, glare, starbursts, or dark shadows.
- **IOL rotation:** The lens shifting out of its optimal position, causing blurred or distorted vision.
- **Glistening:** Tiny reflections within the lens material that may cause light scattering.
- **Blindness:** A very rare but severe outcome

The listed side-effects are to be considered for all Medicontur hydrophobic and hydrophilic IOLs.

7.2 Warnings and side-effects of cataract surgery

While the procedure is highly effective, it is important to be aware of the potential risks and complications that may occur after surgery:

- **Temporary lens opaqueness** caused by significant temperature changes.
- **Postoperative cloudiness**, calcification, or glistening of the implant.
- **Reduced contrast sensitivity** and decreased night vision, especially with trifocal models.
- **Visual disturbances**, such as halos or radial lines around lights.
- **Incorrect refraction**, which may lead to a dissatisfactory visual outcome or continued dependence on glasses.
- **Eye tissue damage or inflammation** inherent to any eye surgery.
- **Increased sensitivity** to UV and blue light, requiring the use of UV-protection sunglasses.
- **Additional surgical intervention**, which may be necessary for lens replacement or extraction if unexpected outcomes or damage occur.

7.3 Complications of 1stQ AddOn® surgery

Rear, but possible incidents of 1stQ AddOn® IOLs under normal conditions of use (expected side-effects):

- **Chronic IOP elevation:** Long-term increased eye pressure that can lead to glaucoma.
- **Interlenticular opacification:** Clouding between lens layers that affects visual performance.
- **TASS (Toxic Anterior Segment Syndrome):** Inflammation of the eye's interior cavity, usually caused by non-infectious factors.
- **Temporarily elevated IOP:** A short-term increase in eye pressure immediately following surgery.
- **Secondary glaucoma:** Raised eye pressure caused by a specific, identifiable medical factor.
- **Endophthalmitis:** A serious infection inside the cavity of the eye.
- **Calcification:** Calcium buildup on the lens surface affecting visual clarity.
- **Dysphotopsia:** Visual disturbances such as glare, halos, or starbursts.
- **IOL rotation:** Shifting of the lens resulting in blurred vision or astigmatism.
- **Pigment dispersion syndrome:** A condition potentially causing increased pressure and glaucoma.
- **Pigment deposits on the IOL:** Buildup on the lens that could potentially affect vision.
- **Cell deposits (macrophages):** Microscopic deposits on the lens that could lead to reduced visual performance.
- **Fibrin deposits:** Protein buildup that could cause cloudiness and decreased clarity.
- **Pupillary capture:** A situation where the iris traps the lens, potentially causing discomfort.

7.4 Warnings and side-effects of 1stQ AddOn® implantation

The safety and effectiveness of Medicontur IOLs have not been studied in patients with certain existing conditions and /or intraoperative complications (as these patients were excluded from clinical studies). In case of any preexisting conditions or complications, consult your ophthalmic surgeon for careful preoperative and perioperative evaluation and clinical judgment to decide the risk/benefit ratio before the implantation of Medicontur IOLs.

- IOL implantation is an invasive procedure, therefore, eye tissue damage, inflammation, or infection might occur occasionally and in the most cases temporarily.
- The artificial material of the IOL may expose the patient to unintended, material-based risks (e.g.: glistening, material fatigue, opacification, leaching).
- Occasionally, under certain circumstances, the 1stQ AddOn® may not meet the expected optical performance (e.g.: PCO, refractive error etc.). Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or may necessitate additional surgical intervention.
- With diffractive models, some patients may experience reduced contrast sensitivity as compared to monofocal IOLs.
- With diffractive models, some patients may experience visual effects because of the superpositioning of focused and unfocused images. Visual effects may include the perception of halos or radial lines around point light sources under low illumination conditions.

7.5 Complications of SML IOL

Additionally, the following side-effects may also be relevant for the model indicated in AMD (A45SML model), based on published side-effects of implantable vision-enhancing devices used in advanced AMD:

- Glare (causing visual discomfort and impaired vision);
- Shadowing of images (unclear or shadowed vision);
- Diplopia for distance vision (double vision when viewing distant objects);
- Narrow field of view (limited peripheral vision);
- Anterior vaulting of the IOL (potentially leading to visual disturbances);
- Pupillary block (possibly causing increased IOP and visual disturbances);
- Explantation because of patient dissatisfaction;
- Sunset syndrome (reduced visual acuity in low light, potentially requiring)

7.6 Complications of Capsular Tension Ring

- Zonular trauma
- Impairments caused during cortical cleansing
- Possible dislocation of the intraocular lens or the capsular bag when the posterior capsular surface tears
- Angle closure

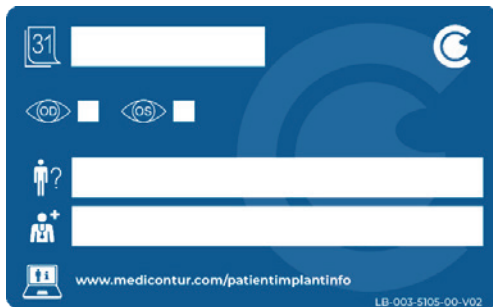
7.7 Warnings and precautions of Capsular Tension Ring

Careful preoperative evaluation and clinical judgment should be made by the surgeon to decide the benefit/risk ratio of the implantation in a patient.

- Capsular Tension Ring implantation is an invasive procedure; therefore, eye tissue damage, inflammation, or infection might occur occasionally.
- The artificial material of the Capsular Tension Ring may expose the patient to unintended, material-based risks (e.g.: material fatigue, leaching).

8. Symbols

Interpretation of symbols included on the Implant Card.



Device name



Information website for patients

PWR

IOL Power

ADD

Add Power of IOL



Unique device identifier
(Note: in barcode format)

UDI-DI

Unique device identifier
(Note: in number format)

IOL

Intraocular lens

SEQ

Spherical equivalent



Date of implantation



Patient name or patient ID



Name and address of the implanting
healthcare institution/provider



Name and address of the
manufacturer



Serial number
(identification number for IOL)



Right Eye



Left Eye

CYL

Cylinder

9. List of Medicontur Ophthalmic Product models

The information provided in this Patient Information Leaflet covers the following intraocular lens models and other ophthalmic medical devices manufactured by Medicontur Ltd.

Model	Brand name	Model	Brand name
613AD	G-Flex	690MTY	Z-Flex Trifocal Toric
640PM	Q-Flex Trifocal Preloaded	690CMY	Trifocal Z-Flex preloaded
640P	Q-Flex Preloaded	690CMTY	Trifocal Toric Z-Flex preloaded
677AD	Bi-Flex	690CTAY	Z-Flex T preloaded
677P	Bi-Flex Preloaded	860FAB	Z-Flex HB
677TA	Bi-Flex T	877FAB	Bi-Flex HB
677M	Trifocal Bi-Flex Liberty	860FABY	Z-Flex HB
677MT	Trifocal Toric Bi-Flex Liberty	877EBY	Bi-Flex ELON HB
677CTA	Bi-Flex T Preloaded	877FABY	Bi-Flex HB
640AD	Q-Flex	860PA	Z-Flex POB-MA
690TA	Z-Flex T	860PT	Z-Flex Toric POB-MA
690CM	Trifocal Z-Flex Preloaded	877PA	Bi-Flex POB-MA
690CTA	Z-Flex T Preloaded	877PT	Bi-Flex Toric POB-MA
690AD	Z-Flex	860PAY	Z-Flex POB-MA
677ADY	Bi-Flex	860PTY	Z-Flex Toric POB-MA
640ADY	Q-Flex	860PEY	Z-Flex EDOF POB-MA
677PY	Bi-Flex Preloaded	860PETY	Z-Flex EDOF Toric POB-MA
677TAY	Bi-Flex T	877PAY	Bi-Flex POB-MA
677MY	Trifocal Bi-Flex Liberty	877PTY	Bi-Flex Toric POB-MA
677MTY	Trifocal Toric Bi-Flex Liberty	877PEY	Bi-Flex ELON POB-MA
677PMY	Trifocal Bi-Flex Liberty Preloaded	877PETY	Bi-Flex ELON Toric POB-MA
677CTAY	Bi-Flex T preloaded	A46R	1stQ AddOn
677CMY	Trifocal Bi-Flex Liberty preloaded	A45RT	1stQ AddOn
677CMTY	Trifocal Toric Bi-Flex Liberty preloaded	A45RD2	1stQ AddOn
640CMY	Trifocal Q-Flex Preloaded	A45DT	1stQ AddOn
640MY	Q-Flex Trifocal	A45SML	Scharioth Macula Lens
640PY	Q-Flex Preloaded	A4EDF1	1stQ AddOn EDOF
690ADY	Z-Flex	A4EDF2	1stQ AddOn EDOF
690TAY	Z-Flex T	11ACB	Jetring 11ACB
690MY	Z-Flex Trifocal	12ACB	Jetring 12ACB

Product availability may vary by country.

All listed ophthalmic medical devices are manufactured by:

Medicontur Medical Engineering Ltd

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