EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 60146676 0001

Manufacturer:
Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Products:
Intraocular Lenses and Ophthalmic Devices
(see attachment for products and additional sites included)

Additional sites included:

Bausch + Lomb, Incorporated
1501 Graves Mill Road
Lynchburg, VA 24502 USA

Bausch + Lomb, Incorporated
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122 USA

Bausch + Lomb, Incorporated
499 Sovereign Court
Manchester, MO 63011 USA

Bausch + Lomb, Incorporated
50 Technology Drive

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 234163243-20

Effective date: 2021-01-18

Expiry date: 2024-05-26

Issue date: 2021-01-18

Digitally signed by Pereteatco Alina
Date: 2021.10.08 12:19:18 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

Song Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Pereteatco Alina
Date: 2021.10.07 23:11:04 EEST

EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 60146676 0001

Manufacturer: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Irvine, CA 92618 USA

Bausch + Lomb, Incorporated
21 Park Place Blvd. N.
Clearwater, FL 33759

Products included:

- Viscoelastics, HPMC (Hydroxypropylmethylcellulose)
- Viscoelastics, bacteria fermented
- IOL, Anterior Chamber PMMA Lenses
- IOL, Posterior Chamber PMMA Lenses
- IOL, Posterior Chamber Lenses, Foldable, Softport and Softflex, and Hydrophilic Acrylic
- IOL, Posterior Chamber Lenses, Foldable, enVista
- IOL, Posterior Chamber Lenses, Foldable, Hydrophobic Acrylic
- Silicone Oil
- Ophthalmic Microsurgical System, Stellaris
- Ophthalmic Microsurgical System, Stellaris PC
- Ophthalmic Microsurgical Handpieces, for Premiere
- Ophthalmic Microsurgical Handpieces, for Millineum
- Ophthalmic Microsurgical Handpieces, for Stellaris PC
- Ophthalmic Microsurgical Handpieces, for Stellaris

Report No.: 234163243-20

Effective date: 2021-01-18

Expiry date: 2024-05-26

Issue date: 2021-01-18

TÜV Rheinland Product Safety GmbH TÜVRheinland Zertifizierungsstelle

Song Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 60146676 0001

Manufacturer: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Products included:

- Ophthalmic Procedure Packs, with energy driven components for Protégé, Premiere, Millennium
- Ophthalmic Procedure Packs, with energy driven components for Stellaris
- Ophthalmic Procedure Packs, with energy driven components for Stellaris PC
- Non-active Ophthalmic Procedure Packs, for Protégé, Premiere, Millennium
- Non-active Ophthalmic Procedure Packs, for Stellaris
- Non-active Ophthalmic Procedure Packs, for Stellaris PC
- Non-active Ophthalmologic Product, Balanced Salt Solution
- Non-active Ophthalmologic Product, sterile Cannula and Cystotomes
- Non-active Ophthalmologic Product, Laseredge knife
- Non-active Ophthalmologic Product, non-sterile Cystotomes
- Non-active Ophthalmologic Product, Infusion/Non-sterile Cannula

Report No.: 234163243-20

Effective date: 2021-01-18

Expiry date: 2024-05-26

Issue date: 2021-01-18

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierstelle

Song Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 60146676 0001

Manufacturer: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Products included:

- Non-active Ophthalmologic Product,
  Lens Insertion Device, disposable - use with Silicone IOLs
- Non-active Ophthalmologic Product,
  Lens Insertion Device, disposable - use with Acrylic IOLs
- Non-active Ophthalmologic Product
  Lens Insertion Device, cartridge with disposable handpiece
- Non-active Ophthalmologic Product,
  Lens Insertion Device, cartridge with reusable handpiece
- Non-active Ophthalmologic Product,
  Independent Viewing Chamber
- Non-active Ophthalmologic Product, Phaco Needle
- Active Ophthalmic Device, Irregation/Aspiration handpiece
- Active Ophthalmic Device, Bipolar Forceps
- Perfluorocarbons, DK-Line, Okta-line

For the following devices the scope covers only the aspect of manufacture concerned with conformity of the products with the metrological requirements:
- Markers, Rulers and Gauges

Report No.: 234163243-20

Effective date: 2021-01-18

Expiry date: 2024-05-26

Issue date: 2021-01-18

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

Song Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

ISO 13485

The State of Maryland

Office of the Secretary of State

This Apostille is not valid for use anywhere within the United States of America, its territories or possessions.

This Apostille does not certify the content of the document for which it is issued.

Apostille

(Convention de La Haye du 5 Octobre 1961)

1. Country: United States of America
   This public document
2. has been signed by **Barbara H. Meiklejohn**
3. acting in the capacity of **Clerk of the Circuit Court for Montgomery County**
4. bears the seal/stamp of the **Circuit Court for Montgomery County**

Certified

5. at Annapolis, Maryland
6. the **14th day of December, 2018**
7. by The Secretary of State of Maryland

Digitally signed by Pereteatco Alina
Date: 2021.10.07 23:11:41 EEST

8. No. 470949
9. Seal

10. Signature

Secretary of State

мною перевода текста документа с английского языка на русский язык

CERTIFICATION

State of Maryland, Montgomery County, Sct.

In the Office of the Clerk of the Circuit Court for Montgomery County

I, Barbara H. Meiklejohn, Clerk of the Circuit Court for Montgomery County, Maryland, a court of ord, hereby certify that DINNA KENCANASARI was a commissioned/ pointed and qualified Notary Public commencing on the 27th day of April, 2018.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the Circuit Court for Montgomery County this 14th day of December, 2018.

Barbara H. Meiklejohn
Clerk of the Circuit Court for Montgomery County

LIC9 20160902

мною перевода текста документа с английского языка на русский язык

CERTIFICATION

tgomery county:

Budi Isyono, hereby declare that the attached document is satisfactory to the best of my nowledge and belief.

Signatory _____
Budi Isyono

SWORN TO AND SUBSCRIBED before me, a notary public for the State of Maryland, this 13th day of December, 2018.

_____
Dinna Kencanasari

Notary public, State of Maryland

My Commission Expires May 30, 2022

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность сведений мною перевода текста документа с английского языка на русский язык

Секацкая Кристина Станиславовна

BELA

H + LOMB
Live better.

1400 North Goodman Street
Rochester, NY 14609
585.338.6000
www.bausch.com

Certified True Copy Letter

belle B. Lefebvre, hereby swear (or affirm) that the attached reproduction of Certificate stration Number:SX 60133519 0001, Quality Management System for sch & Lomb Incorporated, 1400 North Goodman Street, Rochester, NY 14609, USA meets requirements of the standard ISO 13485:2016, and is a true, correct and complete otocopy of the original document on file at Bausch & Lomb Incorporated, 1400 North oodman Street, Rochester, NY 14609, USA.

Isabelle B. Lefebvre, MSc.RA
Vice President, Regulatory Affairs
Bausch & Lomb Incorporated

7 December 2018
Date

State of New Jersey
County of Union
Subscribed and sworn to (or affirmed) before me on this 7th *day of* December, *2018, by* Isabelle B. Lefebvre, *proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.*

Rita E. Moore
Signature of Notary Public

STATE OF NOTARY PUBLIC NEW JERSEY
RITA E MOORE
My Commission Expires
September 19, 2019

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность сделанного мною перевода текста документа с английского языка на русский язык

Секацкая Кристина Станиславовна

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

has established and applies a quality management system for medical devices for the following scope:

Design, development, manufacture, installation, servicing and distribution of medical devices (see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-11-09
Certificate Registration No.:	SX 60133519 0001
An audit was performed. Report No.:	31892411 001
This Certificate is valid until:	2021-10-18

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

мною перевода текста документа с английского языка на русский язык

TÜVRheinland®

Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

achment to
rtificate
gistration No.: SX 60133519 0001
port No.: 31892411 001

Organization: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Scope: Devices included:

- Manual Surgical Instruments for Ophthalmology, Otolaryngology and Plastic- and Reconstructive procedures
- Ophthalmic Surgical Equipment
- Procedure Packs for use with Ophthalmic Surgical Equipment during Cataract and Vitreoretinal procedures
- Intraocular Lenses and Insertion Devices
- Viscoelastics and Retinal Tamponades

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

Секацкая Кристина Станиславовна

TÜVRheinland®

Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

ıchment to
tificate
gistration No.: SX 60133519 0001
port No.: 31892411 001

ırganization: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Scope:

Sites included:

Bausch + Lomb, Incorporated
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122 USA with
499 Sovereign Court
Manchester, MO 63011 USA

Activities associated with the design and development, manufacture, installation, servicing and distribution of:
- Manual Surgical Instruments for Ophthalmology, Otolaryngology and Plastic- and Reconstructive procedures
- Ophthalmic Surgical Equipment
- Procedure Packs for use with Ophthalmic Surgical Equipment during Cataract and Vitreoretinal procedures

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

Секацкая Кристина Станиславовна

TÜVRheinland®

Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

ichment to
tificate
gistration No.: SX 60133519 0001
port No.: 31892411 001

rganization: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Scope:

Sites included:

Bausch + Lomb, Incorporated
21 Park Place Blvd. N.
Clearwater, FL 33759 USA

Activities associated with the design and development, and manufacture of:
- Intraocular Lenses and Insertion Devices

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

мною перевода текста документа с английского языка на русский язык

ОФИС ГОСУДАРСТВЕННОГО СЕКРЕТАРЯ ШТАТА

Апостиль действителен только для использования за пределами Соединенных Штатов Америки, ее
о-территориальных единиц и территорий. Апостиль не удостоверяет содержание документа, в отношении
которого он выдан.

АПОСТИЛЬ
(Гаагская конвенция от 5 октября 1961 года)

рана: Соединенные Штаты Америки

астоящий публично-правовой документ

юдписан Барбарой Х. Миклджон

действующей в качестве секретаря окружного суда округа Монтгомери

имеет печать/штамп окружного суда округа Монтгомери

УДОСТОВЕРЕН

5. в Аннаполис, Мэриленд
6. 14 декабря 2018 года
7. Государственным секретарем штата Мэриленд
8. Печать: Печать Офиса Государственного секретаря штата Мэриленд
9. № 470949
10. Подпись:
    (Подпись)
    Государственный секретарь штата

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

Штат Мэриленд, округ Монтгомери

В офисе секретаря окружного суда округа Монтгомери

Я, Барбара Х. Миклджон, секретарь окружного суда округа Монтгомери, Мэриленд, суда письменного производства, настоящим подтверждаю, что ДИНА КЕНКАНАСАРИ, была должным образом уполномочена/назначена и правомочна исполнять обязанности нотариуса, начиная с 27 апреля 2018 года.

В подтверждение чего я подписала данный документ и скрепила печатью окружного суда округа Монтгомери сего дня 14 декабря 2018 года.

(Подпись)
Барбара Х. Миклджон
Секретарь окружного суда округа Монтгомери
Печать: Окружной суд округа Монтгомери, Мэриленд

ЗАВЕРЕНИЕ

Округ Монтгомери

Я, Буди Исено, настоящим заявляю, что прилагаемый документ является верным, насколько мне известно.

Подпись уполномоченного лица: (подпись)
Буди Исено

ПОДПИСАНО И ПОДТВЕРЖДЕНО ПОД ПРИСЯГОЙ в присутствии нотариуса за и от имени штата Мэриленд 13 декабря 2018 года.

(Подпись)
Дина Кенканасари
Нотариус штата Мэриленд
Срок действия моих полномочий истекает 30 мая 2022 года

Печать: Дина Кенканасари
Нотариус
Округ Монтгомери

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

Бауш & Ломб
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1400 Норт Гудман Стрит
Рочестер, Нью-Йорк 14609
585.338.6000
www.bausch.com

ЗАВЕРЕНИЕ КОПИИ ДОКУМЕНТА

Я, Изабелл Б. Лефевр, настоящим подтверждаю под присягой (или удостоверяю), что прилагаемая копия свидетельства о регистрации SX 60133519 0001, Система менеджмента качества, внедренная компанией Bausch + Lomb Incorporated (Бауш + Ломб Инкорпорейтед), 1400 Норт Гудман Стрит, Рочестер, Нью-Йорк 14609, США, соответствует требованиям стандарта ISO 13485:2016, является верной, точной и полной фотокопией документа, хранящегося в делах компании «Bausch + Lomb Incorporated», (Бауш + Ломб Инкорпорейтед), 1400 Норт Гудман Стрит, Рочестер, Нью-Йорк, США.

(Подпись)
Изабелл Б. Лефевр, магистр наук
Вице-президент по вопросам
нормативно-правого регулирования
Бауш + Ломб Инкорпорейтед

7 декабря 2018 года
Дата

Штат Нью-Джерси

Округ Юнион

Подписано и подтверждено под присягой (удостоверено) в моем присутствии 7 декабря 2018 года Изабелл Б. Лефевр, подтвердившей мне на основании соответствующих документов, удостоверяющих личность, что является лицом, представшим передо мною.

(Подпись)
Подпись нотариуса

Штамп: Рита И. Мур
Нотариус – Штат Нью-Джерси
Срок действия моих полномочий истекает
19 сентября 2019 года

Печать: Рита И. Мур
Нотариус
Штат Нью-Джерси
Срок действия моих
полномочий истекает
19 сентября 2019 года

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

ТЮФРайнланд

СЕРТИФИКАТ

Орган по сертификации «ТЮФ Райнланд ЛГА Продактс ГмбХ»

настоящим подтверждает, что компания

Bausch + Lomb, Incorporated
(Бауш + Ломб, Инкорпорейтед)
1400 Норт Гудман Ст.
Рочестер, Нью-Йорк 14609
США

внедрила и применяет систему менеджмента качества для изделий медицинского назначения для следующей сферы деятельности:

Проектирование, разработка, производство, монтаж, обслуживание и распространение изделий медицинского назначения
(смотри приложение касательно продукции и дополнительных производственных предприятий)

В ходе проверки были получены доказательства того, что требования

EN ISO 13485:2016

соблюдаются. Система менеджмента качества подвергается ежегодным проверкам.

Дата вступления в силу: 09.11.2018

Регистрационный номер сертификата: SX 60133519 0001

Номер отчета о проведении аудиторской проверки: 31892411 001

Данный сертификат действителен до 18.10.2021

Орган по сертификации
(Подпись)
Роланд Грубер

Печать: ТЮФ Райнланд ЛГА Продактс ГмбХ. Орган по сертификации

DAkkS
Национальный немецкий орган по аккредитации
D-ZM-14169-01-02

ТЮФ Райнланд ЛГА Продактс ГмбХ, Тиллиштрассе 2, 90431 Нюрнберг
Тел. +49 221 806-1371, факс: +49 221 806-3935, e-mail: cert-validity@de.tuv.com, http://www.tuv.com/safety

Дата: 09.11.2018

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

ТЮФ Райнланд
ТЮФ Райнланд ЛГА Продактс ГмбХ
Тиллиштрассе 2, 90431 Нюрнберг

Приложение к сертификату
Регистрационный номер: SX 60133519 0001

Номер отчета: 31892411 001

Производитель: Bausch + Lomb, Incorporated
(Бауш + Ломб, Инкорпорейтед)
1400 Норт Гудман Ст.
Рочестер, Нью-Йорк 14609
США

Вид деятельности: Включены инструменты:
- ручные хирургические инструменты для офтальмологии, отоларингологии, пластической- и восстановительной хирургии
- офтальмологические хирургические инструменты
- наборы для выполнения процедуры с использованием офтальмологических хирургических инструментов при катаракте и витреоретинальной хирургии
- интраокулярные линзы и системы ввода
- вискоэластики и тампонада витреальной полости

Орган по сертификации
(Подпись)
Роланд Грубер

Печать: ТЮФ Райнланд ЛГА Продактс ГмбХ. Орган по сертификации

DAkkS
Национальный немецкий орган по аккредитации
D-ZM-14169-01-02

Дата: 09.11.2018

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

Секацкая Кристина Станиславовна

ТЮФ Райнланд
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Приложение к сертификату
Регистрационный номер: SX 60133519 0001

Номер отчета: 31892411 001

Производитель:

Bausch + Lomb, Incorporated
(Бауш + Ломб, Инкорпорейтед)
1400 Норт Гудман Ст.
Рочестер, Нью-Йорк 14609
США

Вид деятельности:

Дополнительное предприятие:

Bausch + Lomb, Incorporated
3365 Три Корт Индастриал Блвд.
Ст. Луис, Миссури 63122 США, а также
499 Соверейн Корт
Манчестер, Миссури 63011 США

Деятельность, связанная с разработкой и проектированием, производством, монтажом, обслуживанием и распространением:
- ручные хирургические инструменты для офтальмологии, отоларингологии, пластической- и восстановительной хирургии;
- офтальмологические хирургические инструменты
- наборы для выполнения процедуры с использованием офтальмологических хирургических инструментов при катаракте и витреоретинальной хирургии

Орган по сертификации
(Подпись)
Роланд Грубер

Печать: ТЮФ Райнланд ЛГА Продактс ГмбХ. Орган по сертификации

DAkkS
Национальный немецкий орган по аккредитации
D-ZM-14169-01-02

Дата: 09.11.2018

Я, переводчик Секацкая Кристина Станиславовна, подтверждаю достоверность совершенного мною перевода текста документа с английского языка на русский язык

ТЮФ Райнланд
ТЮФ Райнланд ЛГА Продактс ГмбХ
Тиллиштрассе 2, 90431 Нюрнберг

Приложение к сертификату
Регистрационный номер: SX 60133519 0001

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Производитель:
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1400 Норт Гудман Ст.
Рочестер, Нью-Йорк 14609
США

Вид деятельности:
Дополнительное предприятие:

Bausch + Lomb, Incorporated
21 Парк Плэйс Блвд. Н.
Клируотер, Флорида 33759, США

Деятельность, связанная с разработкой и проектированием, производством:
- интраокулярные линзы и системы ввода

Орган по сертификации
(Подпись)
Роланд Грубер

Печать: ТЮФ Райнланд ЛГА Продактс ГмбХ. Орган по сертификации

DAkkS
Национальный немецкий орган по аккредитации
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Город Минск, Республика Беларусь. Четвёртое января две тысячи девятнадцатого года.

Я, Кашинская Валентина Цезаревна, нотариус Минского городского нотариального округа (свидетельство на осуществление нотариальной деятельности № 731, выданное Министерством юстиции Республики Беларусь 28 мая 2014 г.), свидетельствую подлинность подписи известного мне переводчика Секацкой Кристины Станиславовны.

Зарегистрировано в реестре за № 4-8.
Взыскано нотариального тарифа 17 рублей 85 копеек.

Нотариус

В настоящем документе прошито и скреплено печатью на пятнадцати листах.

Нотариус

Bausch&Lomb

Akreos ®

Lentlă acrilică de adaptare
Lentilă asferică cu optică avansată

LENTILE INTRAOCULARE

DESCRIERE: Lentilele intraoculare (LIO) flexibile Akreos sunt lentile fabricate dintr-o singură piesă din copolimer acrilic hidrofil care conține absorbant UV. Puterile disponibile pot varia în funcție de lungimea totală a modelelor (consultați broșura). Compoziția și caracteristicile specifice fiecărei LIO sunt specificate pe eticheta de pe ambalaj.

INDICAȚII: Lentilele de cameră posterioară Akreos sunt indicate pentru implantare primară pentru corectarea vizuală a afachiei la pacienții adulți la care un cristalin afectat de cataractă a fost îndepărtat prin metode de extracție extracapsulară. Lentila este concepută pentru implantare în sacul capsular după extracție de cataractă extracapsulară.

CONTRAINDICAȚII: Implantarea nu este recomandată atunci când lentila poate agrava o afecțiune existentă, să interfereze cu diagnosticul sau tratamentul unei patologii sau prezintă risc pentru vederea pacientului. Aceste afecțiuni sunt: glaucom necontrolat, cataractă rubeolică, dezlipirea de retină, atrofia irisului, microftalmie, infecții oculare cronice în dezvoltare, distrofie corneană endotelială, complicații pe-operative (cum ar fi pierderea vitroasă, hemoragie), complicații postoperatorii previzibile.

AVERTISMENT: Ca și în toate procedurile chirurgicale, intervenția chirurgicală pentru cataractă cu implantare de LIO prezintă riscuri pe care chirurgul trebuie să le evalueze. Complicațiile potențiale ale intervenției chirurgicale pentru cataractă sunt: inflamație (iridociclite, membrana pupilară, inflamație vitroasă, CME), infecție (endoftalmită), dezlipirea de retină, blocaj papilar, hernie a irisului, aplatizare a camerei anterioare, hemoragie (hifema), distrofie corneană, glaucom, atrofie a irisului. Printre cele legate direct de LIO sunt: descentrare și subluxație, precipitatele de pe suprafața uleiului de silicon al LIO, în special atunci când este utilizată în tratamentul chirurgical al dezlipirei de retină, se pot lipi de LIO dacă capsula posterioară a cristalinului nu este intact.

MBALARE/STERILIZARE: LIO Akreos sunt ambalate individual într-un flacon de sticlă și o husă care trebuie să fie deschise în condiții sterile. LIO Akreos sunt prezentate într-un dispozitiv care permite ținerea și plierea simultană a implantului. Cartea pacientului și etichetele autoadezive de identificare a implantului asigură monitorizarea medicală a pacientului și oferă posibilitatea de trasabilitate a lentilei intraoculare. Acestea sunt furnizate în cutie de carton care conține instrucțiunile de utilizare (diagrama și caracteristicile lentilei intraoculare, numărul de serie, data de expirare ...). LIO Akreos sunt sterilizate cu abur.

PRECAUȚII DE UTILIZARE ȘI DEPOZITARE: A se păstra la temperatura camerei. A se evita temperaturile ridicate (> 45°C). De unică folosință. A nu se resteriliza. A nu se utiliza LIO dacă cutia de carton și integritatea sigiliului acesteia au fost deschise sau deteriorate. LIO

trebuie utilizată în cel mai scurt timp posibil după deschiderea flaconului. Modelul LIO, data de expirare și puterea trebuie verificate înainte de a deschide ambalajul de protecție și înainte de a deschide punga individuală sterilă. Sterilitatea lentilei intraoculare este garantată numai dacă punga individuală sterilă nu a fost deschisă sau deteriorată. LIO Akreos pot absorbi substanțele cu care vin în contact (medicament dezinfectant...). În consecință, lentilele Akreos trebuie să fie atent clătite cu soluție salină echilibrată sterilă. Dacă se realizează o capsulotomie posterioară cu laser YAG, asigurați-vă că fascicolul laserului este focalizat ușor în spatele capsulei posterioare.

MOD DE UTILIZARE: Deschideți cutia și scoateți punga sterilizată care conține flaconul cu lentile. Desprindeți treptat punga și plasați flaconul cu lentile pe o suprafață sterilă. Înainte de a deschide flaconul cu lentile, faceți o verificare finală a LIO și putererii acesteia.

Tehnica de deschidere a flaconului:

- Rotiți capacul invers acelor de ceasornic pentru a-l înlătura.
- Înlăturați capacul flaconului.

Fig. 1-1: Apăsați cu atenție pe o parte a limbii dispozitivului de fixare-pliere cu degetul mare, în timp ce degetul arătător este pe partea opusă până când flaconul începe să se deschidă. Evitați exercitarea unei presiuni excesive, deoarece flaconul se poate deschide brusc, iar fălcile pot lovi interiorul flaconului cu o forță suficientă pentru a provoca căderea lentilelor din flacon.

Fig. 1-2: Trageți cu atenție fila pentru a deschide flaconul complet. Examinați lentilele cu atenție și clătiți cu soluție salină sterilă. Trebuie utilizate doar instrumente de inserție care au fost validate și aprobate pentru utilizarea cu aceste lentile. Notă: Pentru informații suplimentare Vă rugăm să consultați Instrucțiunile de Utilizare pentru instrumentul de inserție.

ORIENTAREA LENTILELOR: În cazul lentilelor de modelul Adapt-AO, lentila se implantează cu partea anterioară în sus spre partea anterioara a ochiului. Orientarea LIO poate fi verificată prin inspectarea vizuală a hapticelui. Așa cum este ilustrat în figura 2-1, atunci când caracteristicile hapticelui sunt dreapta sus B și stânga jos A, sunteți cu fața spre partea anterioară a cristalinului.

AKREOS® FOLD:
(Vă rugăm să consultați diagramele anexate):

A) Plierea lentilelor:

Fig. 3-1: Așezați degetul mare și arătător pe punctele de presiune ale dispozitivului de pliere.

Fig. 3-2: Apăsați fălcile dispozitivului de pliere. Veți auzi un clic la blocarea dispozitivului.

Fig. 3-3: Îndepărtați lentilele pliate cu un forceps de implantare. Acest forceps trebuie să fie paralel cu fălcile dispozitivului.

B) Menținerea lentilei depliate:

Fig. 4-1: Nu activați sistemul de pliere. Utilizați ca un forceps de ținere. Scoateți lentilele apucând elementul optic de-a lungul axei între poziția acelor ceasornice 6-12.

CARACTERISTICI FIZICE:

Indice de refracție al lentilelor atunci când sunt ude la 20°C = 1.459

Indice de refracție al lentilelor atunci când sunt în ochi 35°C = 1.458.

GARANȚIE: Bausch & Lomb Incorporated garantează că lentilele intraoculare sunt livrate în conformitate cu legislația în vigoare și versiunea curentă a producătorului cu privire la specificațiile publicate referitoare la aceste lentile intraoculare sub toate aspectele materiale și fără defecte materiale sau de fabricație.

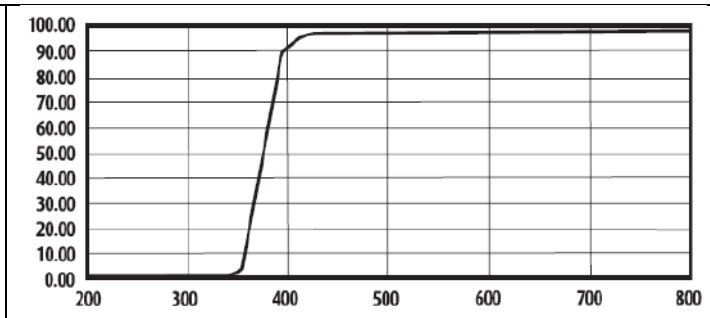
BAUSCH & LOMB INCORPORATED EXCLUDE TOATE CELELALTE GARANȚII, EXPRIMATE, IMPLICITE SAU DE PLIN DREPT SAU DE ALTFEL, INCLUSIV, DAR FĂRĂ A SE LIMITA LA ORICE GARANȚII IMPLICITE DE VANDABILITATE SAU POTRIVIRE PENTRU UN ANUMIT SCOP. BAUSCH & LOMB INCORPORATED NU VA FI RĂSPUNZĂTOR PENTRU DAUNE, PIERDERI SAU CHELTUIELI ACCIDENTALE, DE CONSECINȚĂ SAU EXEMPLARE, CARE REZULTĂ DIRECT SAU INDIRECT DIN UTILIZAREA DISPOZITIVULUI DE INSERȚIE DE UNICĂ FOLOSINȚĂ AKREOS, CHIAR DACĂ BAUSCH & LOMB INCORPORATED A FOST AVERTIZAT DESPRE POSIBILITATEA UNOR ASTFEL DE DAUNE, PIERDERI SAU CHELTUIELI.

POLITICA DE RETURNARE

Toate produsele returnate la Bausch & Lomb Incorporated trebuie să fie însoțite de Numărul autorizației de returnare a produsului eliberat de Serviciul Clienți Bausch & Lomb. Flacoanele deschise sau nedeschise vor fi scimbate contra unei sume echivalente în dolari, cu condiția că produsele nu au depășit termenul de valabilitate. Pot fi evaluate taxe de reprocesare pentru lentilele care au depășit data de expirare. Acest lucru este valabil pentru produsele deschise sau nedeschise. Nu este politica Bausch & Lomb de a emite rambursări de credit sau numerar pentru lentilele returnate.

COMPETENȚE LENTILE DISPONIBILE: Lentile intraoculare Akreos sunt furnizate în dioptrii variind de la +0 la +30 (D) cu pași de 0.5D sau 1D în funcție de model și gama de dioptrie.

F	**CURBA DE TRANSMISIE UV**



Bausch & Lomb Incorporated
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EC REP

Bausch & Lomb Incorporated
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Locul de producție:
Bausch & Lomb
Chauvin Opsia
580, rue Max Planck
31670 Labège
Franța

2

STERILE

CE 0197

BAUSCH + LOMB

See better. Live better.

Bausch + Lomb develops and markets a **full portfolio of products.** Its expertise in ophthalmology and innovation both contribute to make **Bausch + Lomb a reference in the field of international eye care.**

The Bausch + Lomb portfolio **offers a solution to all ocular surgical needs:**

- Intraocular lenses (IOLs)
- Viscoelastics
- Instruments
- Equipment and disposables
- Other ophthalmic devices

BAUSCH + LOMB

MONOFOCAL HYDROPHILIC MICRO-INCISION

AKREOS® MICS™

MICRO-INCISION ONE-PIECE HYDROPHILIC ACRYLIC IOL

Ref **MI60Pxxxx**

MATERIAL

Hydrophilic Acrylic
26 % water content
UV-blocker
Refractive Index: 1.46

DESIGN

Monofocal Aberration-Free Aspheric Optic
360° posterior square edge
10° haptic angulation
One-piece IOL with four-point fixation
Orientation features to indicate the anterior side

Optic diameter	6.2 mm from 0.0 D to +15.0 D 6.0 mm from +15.5 D to +22.0 D 5.6 mm from +22.5 D to +30.0 D
Overall diameter	11.0 mm from 0.0 D to +15.0 D 10.7 mm from +15.5 D to +22.0 D 10.5 mm from +22.5 D to +30.0 D

DIOPTER RANGE

From 0.0 D to +30.0 D	0.0 D to +10.0 D in 1.0 D increments +10.0 D to +30.0 D in 0.5 D increments

INJECTORS

Viscoject™ BIO 1.8 LP604350C (10/box)
Recommended incision size: 1.8 mm WAT

Comport PLUS 1.8 INJRET18 (1/box)
Recommended incision size: 1.8 mm WAT

CONSTANTS*

Immersion A-Scan or IOL Master	A-Constant: SRK/T: 119.1 ACD: 5.67 Surgeon Factor: 1.90 Haigis Constant: a_0: 1.49 / a_1: 0.40 / a_2: 0.10
Applanation A-Scan	A-Constant: 118.4 ACD: 5.20 Surgeon factor: 1.45

*** Constants are estimates only (source: ULIB Optimized IOL Constant, http://www.augenklinik.uni-wuerzburg.de/ulib/c1.htm)**
It is recommended that each surgeon develops their own values.
Latest update: June 2017

MONOFOCAL HYDROPHILIC MICRO-INCISION

AKREOS® MICS™
INTRAOCULAR LENS

1.8 mm MICS™ is a reality
The Vital Element For a Successful MICS™ Surgery

1.8 mm MICS™ Requires The Material Difference

- Akreos® MICS™ Lens is crafted from a Bausch + Lomb proprietary acrylic material
- The lens can be compressed easily to fit through a 1.8 mm incision

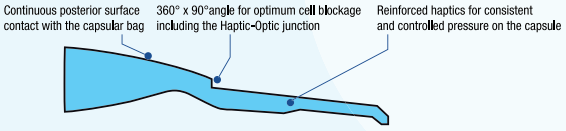
3-Dimensional Stability

- The innovative shape of the Akreos® MICS™ has been designed to optimise its post-operative behaviour in the capsular bag and to allow for the absorption of forces in 3 dimensions
- 360° posterior square edge barrier to prevent against PCO

Quality of vision

- Akreos® Aspheric Abberation-Free
- Four-point fixation haptic design for optimal stability and centration in the capsular bag

Enhanced Mechanical Barriers



For more information on content and clinical sources, please refer to the IOL sales materials.

BAUSCH + LOMB

MONOFOCAL | HYDROPHILIC | MINI-INCISION

AKREOS® ADAPT AO

ONE-PIECE HYDROPHILIC ACRYLIC IOL

Ref **ADAPTAOPxxxx**

MATERIAL

Hydrophilic Acrylic
26 % water content
UV-blocker
Refractive index: 1.46

DESIGN

Monofocal Aberration-Free Aspheric Optic
360° posterior square edge
One-piece with four-point fixation

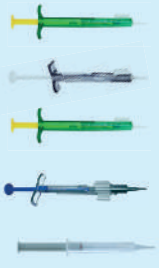
Optic diameter	6.0 mm from +10.0 D to +30.0 D 6.2 mm from 0.0 D to +9.0 D
Overall diameter	11.0 mm from 0.0 D to +15.0 D 10.7 mm from +15.5 D to +22.0 D 10.5 mm from +22.5 D to +30.0 D

DIOPTER RANGE

From 0.0 D to +30.0 D	0.0 D to +10.0 D in 1.0 D increments +10.0 D to +30.0 D in 0.5 D increments

INJECTORS

Viscoject™ BIO 1.8 LP604350C (10/box)
Recommended incision size: 1.8 mm WAT
Comport PLUS 2.2 INJRET22 (1/box)
Recommended incision size: 2.2 mm WAT
Viscoject™ 2.2 LP604340 (10/box)
Recommended incision size 2.2 mm WAT
INJ100 (10/box)
Recommended incision size: 2.2 mm WAT
Hydroport AI-28 (1/box)
Recommended incision size 2.8 mm in the bag



CONSTANTS*

Immersion A-Scan or IOL Master	A-Constant: SRK/T: 118.5 ACD: 5.26 Surgeon Factor: 1.51 Haigis Constant: a_0: -0.83 / a_1: 0.305 / a_2: 0.191
Applanation A-Scan	A-Constant: 118.0 ACD: 4.96 Surgeon Factor: 1.22

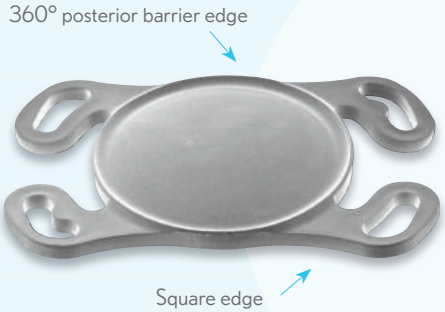
*** Constants are estimates only (source: ULIB Optimized IOL Constant, http://www.augenklinik.uni-wuerzburg.de/ulib/c1.htm) Latest update: June 2017**

MONOFOCAL | HYDROPHILIC | MINI-INCISION

AKREOS® ADAPT AO
INTRAOCULAR LENS

A vision that patients can appreciate

- Aberration-Free aspheric optic to improve image quality, enhance depth of field and be more tolerant to lens misalignment
- Akreos® Adapt AO is designed to provide predictable, repeatable refractive outcomes for all cataract patients
- 360° posterior square edge for optimised effectiveness against PCO
- Four-point fixation designed for stability and centration



For more information on content and clinical sources, please refer to the IOL sales materials.

BAUSCH + LOMB

MONOFOCAL | HYDROPHOBIC | MINI-INCISION

enVista®

ONE-PIECE HYDROPHOBIC ACRYLIC IOL

Ref **MX60Pxxxx**

MATERIAL

Glistening-Free Hydrophobic Acrylic
4 % water content
UV-blocker
Refractive index: 1.54

DESIGN

Monofocal Aberration-Free Aspheric Optic
Step-vaulted haptics; Modified C-loop haptics
360° posterior square edge
Fenestrated haptics
Optic diameter: 6.0 mm
Overall diameter: 12.5 mm

DIOPTER RANGE

From 0.0 D to +34.0 D	0.0 D to +10.0 D in 1.0 D increments +10.0 D to +30.0 D in 0.5 D increments +30.0 D to +34.0 D in 1.0 D increments

INJECTORS

Reusable BLIS-R1

with single-use cartridge BLIS-X1 from +10.0 D to +34.0 D (10/box)
Recommended incision size: 2.2 mm WAT

INJ100 (10/box)
Recommended incision size: 2.2 mm WAT

CONSTANTS*

Immersion A-Scan and IOL Master	A-Constant SRK/T: 119.1 ACD: 5.61 Surgeon Factor: 1.85 Haigis Constant: a_0: 1.46 / a_1: 0.40 / a_2: 0.10
Applanation A-Scan	A-Constant: 118.7 ACD: 5.37 Surgeon Factor: 1.62

*** Constants are estimates only.**
It is recommended that each surgeon develops their own values.
Latest update: June 2017

MONOFOCAL HYDROPHOBIC MINI-INCISION

enVista®
INTRAOCULAR LENS

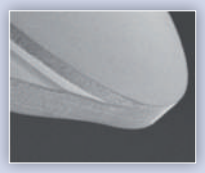
Glistenings do exist. But not for enVista®

Quality of Vision
- Pre-hydrated (0.9 % saline solution) to equilibrium to prevent glistening formation
- No glistenings detected at any time in a 2-year prospective study[1,2]
- Abrasion resistance is increased due to improved surface durability[3]

Designed to Minimise PCO
- Step-vaulted haptics
- 360° posterior square edge[4]

Advanced Ease of Use
- Safe, simple, reliable insertion through a 2.2 mm incision
- Easy positioning in the capsular bag by controlled unfolding

Designed to minimise PCO

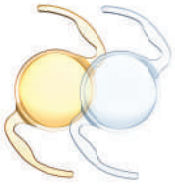


1. enVista® Directions for Use.
2. Tetz MR, Werner L, Schwahn-Bendig S, Batlle JF. A prospective clinical study to quantify glistenings in a new hydrophobic acrylic IOL. Paper presented at: American Society of Cataract and Refractive Surgery (ASCRS) Symposium & Congress; April 3-8, 2009; San Francisco, CA.
3. Mentak K, Martin P, Elachchabi A, Goldberg EP. Nanoindentation studies on hydrophobic acrylic IOLs to evaluate surface mechanical properties. Paper presented at: XXV Congress of the European Society of Cataract and Refractive Surgery; September 8-12, 2007; Stockholm, Sweden.
4. Nishi O, Nishi K, Osakabe Y. E ect of intraocular lenses on preventing posterior capsule opacification: design versus material. J Cataract Refract Surg. 2004;30(10):2170-2176.

For more information on content and clinical sources, please refer to the IOL sales materials.

BAUSCH + LOMB

MONOFOCAL | HYDROPHOBIC | PRELOADED MINI-INCISION



EyeCee® ONE / EyeCee® ONE CRYSTAL

ONE-PIECE HYDROPHOBIC ACRYLIC IOL

Preloaded Ref **EYEC1PREXXXX / EYEC1CRYPREXXXX**

Non preloaded Ref **EYEC1XXXX / EYEC1CRYXXXX**

MATERIAL

Hydrophobic Acrylic
UV-blocker
Blue-light blocker (for EyeCee® ONE only)
Refractive index: 1.52

DESIGN

Monofocal Negative Aspheric Optic
Modified C-loop
360° posterior square edge
Optic diameter: 6.0 mm
Overall diameter: 13.0 mm

DIOPTER RANGE

Preloaded From +11.0 D to +30.0 D	+11.0 D to +30.0 D in 0.5 D increments

Recommended incision size: 2.4 mm in the bag
(please refer to the DFU)

EyeCee® ONE Non preloaded From +1.0 D to +30.0 D	+1.0 D to +10.0 D in 1.0 D increments +10.0 D to +27.0 D in 0.5 D increments +27.0 D to +30.0 D in 1.0 D increments
EyeCee® ONE CRYSTAL Non preloaded From +1.0 D to +10.5 D	+1.0 D to +10.0 D in 1.0 D increments 10.5 D

INJECTORS

MDJ 2.0 - 2.2 MDJ20-22 (1/box)
Recommended incision size: 2.2 mm WAT

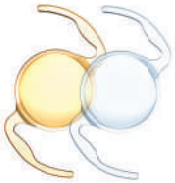
MDJ LOADINJECT® 2.2 8000001533 (1/box)
Recommended incision size: 2.2 mm WAT

CONSTANTS*

Immersion A-Scan and IOL Master	A-Constant SRK/T: 119.7 ACD: 6.0 Surgeon Factor: 2.13 Haigis Constant: a_0: 1.675 / a_1: 0.40 / a_2: 0.10
Applanation A-Scan	A-Constant: 119.1 ACD: 5.70 Surgeon Factor: 1.73

*** Constants are estimates only.**
It is recommended that each surgeon develops their own values.
Latest update: June 2017

MONOFOCAL | HYDROPHOBIC | PRELOADED MINI-INCISION



EyeCee® ONE / EyeCee® ONE CRYSTAL

INTRAOCULAR LENSES

Fully Preloaded Hydrophobic IOL

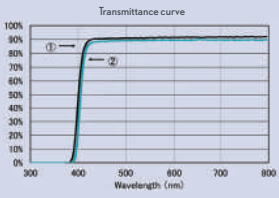
- An easy 2-step procedure with a short learning curve (please refer to the IFU and loading guide)
- 2.4mm incision in-the-bag (please refer to the loading guide)
- Single use injector

Quality of Vision

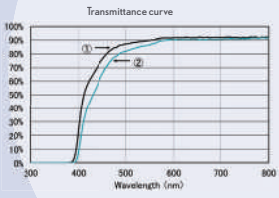
- Asperitic optic edge to reduce glare phenomena
- Negative aspheric optic design (-0.13 µm) to compensate for positive corneal spherical aberrations (SA)
- 90° anchor wing haptic with large contact angle for optimized intra-capsular bag behaviour of the lens
- Unique haptic design to maximize intracapsular bag fixation and long-term stability
- 360° posterior square edge to reduce PCO
- Blue-light filter (for EyeCee® ONE only)

Spectral Light Transmission

EyeCee® ONE CRYSTAL



EyeCee® ONE with moderate blue-light filter



Curve ①: Spectral Transmittance curve of a typical 1.0D IOL (thinnest).

Curve ②: Spectral Transmittance curve of a typical 30.0D IOL (thickest).

For more information on content and clinical sources, please refer to the IOL sales materials.

BAUSCH + LOMB

MONOFOCAL | HYDROPHOBIC | 3-PIECE PRELOADED

EyeCee®

THREE-PIECE HYDROPHOBIC ACRYLIC IOL

Ref **EYECPRExxxx**

MATERIAL

Optic: Hydrophobic Acrylic
Haptic: PMMA
UV-blocker
Refractive index: 1.52

DESIGN

Monofocal optic
J-loop haptics
Square edges
7° haptic angulation
Optic diameter: 6.0 mm
Overall diameter: 12.5 mm

DIOPTER RANGE

Preloaded	+10.0 D to +27.0 D in 0.5 D increments
From +10.0 D to +28.0 D	+27.0 D to +28.0 D in 1.0 D increments

Recommended incision size: 2.8 mm in the bag

CONSTANTS*

Immersion A-Scan and IOL Master	A-Constant SRK/T: 119.5 ACD: 5.87 Surgeon Factor: 2.11 Haigis Constant: a_0: 1.73 / a_1: 0.40 / a_2: 0.10
Applanation A-Scan	A-Constant: 119.2 ACD: 5.66 Surgeon Factor: 1.90

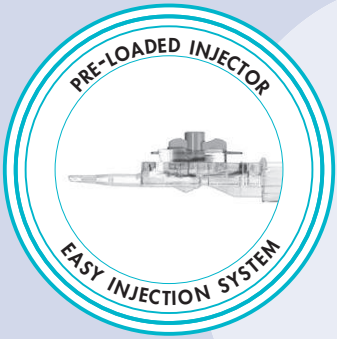
*** Constants are estimates only.**
It is recommended that each surgeon develops their own values.
Latest update: June 2017

MONOFOCAL | HYDROPHOBIC | 3-PIECE PRELOADED

EyeCee®
INTRAOCULAR LENS

3-Piece Hydrophobic Preloaded IOL

- Preloaded injection system for safe and easy handling
- Damage of the implant is avoided
- No risk of dangerous cross-contaminations
- Square edge for prevention of PCO



For more information on content and clinical sources, please refer to the IOL sales materials.

BAUSCH + LOMB

TORIC | HYDROPHOBIC | MINI-INCISION

enVista® TORIC

ONE-PIECE HYDROPHOBIC ACRYLIC TORIC IOL

Ref **MX60TPxxxx**

MATERIAL

Glistening-Free Hydrophobic Acrylic
4 % water content
UV-blocker
Refractive index: 1.54

DESIGN

One-Piece, Aberration-Free Aspheric Optic
Step-vaulted haptics; Modified C-loop haptics
360° posterior square edge
Fenestrated haptics
Optic diameter: 6.0 mm
Overall diameter: 12.5 mm

DIOPTER RANGE

From +6.0 D to +30.0 D in 0.5 D increments	Cylinder powers-IOL plane: +1.25 D / +2.00 D / +2.75 D / +3.50 D / +4.25 D / +5.00 D / +5.75 D Cylinder powers-corneal plane: +0.90 D / +1.40 D / +1.93 D / +2.45 D / +2.98 D / +3.50 D / +4.03 D

INJECTORS

Reusable BLIS-R1
with single-use cartridge BLIS-X1 from +10.0 D to +34.0 D (10/box)
Recommended incision size: 2.2 mm WAT

INJ100 (10/box)
Recommended incision size: 2.2 mm WAT

CONSTANTS*

Immersion A-Scan and IOL Master	A-Constant SRK/T: 119.1 ACD: 5.61 Surgeon Factor: 1.85 Haigis Constant: a_0: 1.46 / a_1: 0.40 / a_2: 0.10
Applanation A-Scan	A-Constant: 118.7 ACD: 5.37 Surgeon Factor: 1.62

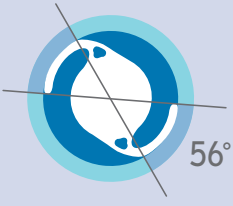
*** Constants are estimates only.**
It is recommended that each surgeon develops their own values.
Latest update: June 2017

TORIC | HYDROPHOBIC | MINI-INCISION

enVista® TORIC
INTRAOCULAR LENS

Lock in superior rotational stability[1]
Unique haptics are designed to secure a predictable astigmatism correction

- Glistening-Free Hydrophobic Acrylic
- The ideal combination of stable performance and predictability
- Aberration-Free Aspheric
- Fenestrated, step-vaulted haptics with 56° Contact angle and square posterior edge optic are designed to optimize 360° Capsular contact[2]
- 360° posterior square edge with haptic-optic junction designed to minimise PCO
- Polished for a smooth optic surface



Unique fenestrated, step-vaulted haptics with 56° contact angle are designed to maximise stability

- **91%** of patients had ≤ **5°** rotation from day of surgery to 6 months[1]
- **3°** absolute mean rotation at 6 months[1]
- **0.28 mm** mean decentration[1]

1. Packer M and al. Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista). Clinical Ophthalmology 2013;7:1905–1912
2. Nishi O, Nishi K, Osakabe Y. Effect of intraocular lenses on preventing posterior capsule opacification: design versus material. J Cataract Refract Surg. 2004;30(10):2170-2176

BAUSCH + LOMB

MONOFOCAL | 3-PIECE SEMI-LOADED | SILICONE

SOFPORT® AO

3-PIECE ASPHERIC IOL SEMI-LOADED

Ref **LI61AORxxxx**

MATERIAL

Optic: Silicone
Haptics: PMMA
UV-blocker
Refractive index: 1.43

DESIGN

Monofocal Aberration-Free Aspheric Optic
C-modified haptics
5° angulation
360° posterior square edge
Optic diameter: 6.0 mm
Overall diameter: 13.0 mm
In the bag or ciliary sulcus

DIOPTER RANGE

From 0.0 D to +34.0 D

0.0 D to +4.0 D in 1.0 D increments
+5.0 D to +30.0 D in 0.5 D increments
+31.0 D to +34.0 D in 1.0 D increments

INJECTOR

Easy-Load (semi-loaded) EZ-24 (1/box)
Recommended incision size: 2.4 mm in the bag

CONSTANTS*

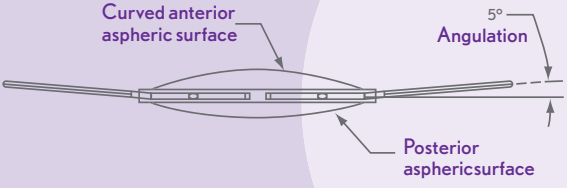
Immersion A-Scan and IOL Master	A-Constant SRK/T: 118.7 ACD: 5.40 Surgeon Factor: 1.62 Haigis Constant: a_0: 0.057 / a_1: 0.186 / a_2: 0.171
Applanation A-Scan	A-Constant: 118.0 ACD: 5.00 Surgeon Factor: 1.22

*** Constants are estimates only.**
It is recommended that each surgeon develops their own values.
Latest update: June 2017

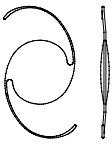
MONOFOCAL | 3-PIECE SEMI-LOADED | SILICONE

SOFPORT® AO
INTRAOCULAR LENS

- Foldable 3-piece IOL
- Aberration-Free Aspheric Optic
- Moderate refractive index and curved anterior surface
- 360° posterior square edge and 5° angulation designed for optimum PCO minimisation
- Predictable and stable refractive outcomes
- Semi-loaded injector to facilitate lens insertion: easy to fold and controlled unfolding



BAUSCH + LOMB



PMMA EZE-60

ONE PIECE PMMA
POSTERIOR CHAMBER IOL

Ref **8Axxx**

MATERIAL PMMA, UV-blocker, Refractive index: 1.49

DESIGN Monofocal optic, Spherical, C-modified, flexible haptics, 3° angulation, Optic diameter: 6.0 mm – Overall diameter: 12.75 mm

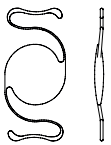
DIOPTER RANGE

From +10.0 D to +30.0 D in 0.5 D increments

CONSTANTS*

Applanation A-Scan

A-Constant: 118.1
ACD: 5.02
Surgeon Factor: 1.28



PMMA L122UV

ONE PIECE PMMA
ANTERIOR CHAMBER IOL

Ref **8Uxxx**

MATERIAL PMMA, UV-blocker, Refractive index: 1.49

DESIGN Monofocal optic, Spherical, One piece IOL with four point fixation, Flexible, S-modified haptics, 3.7° angulation Optic diameter: 6.0 mm – Overall diameter: 13.75 mm

DIOPTER RANGE

From +5.0 D to +30.0 D in 0.5 D increments

CONSTANTS*

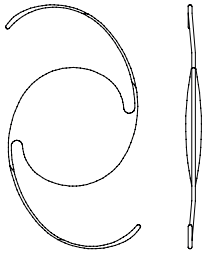
Applanation A-Scan

A-Constant: 115.8
ACD: 3.68
Surgeon Factor: -0.02

*** Constants are estimates only.**
It is recommended that each surgeon develops their own values.
Latest update: June 2017

MONOFOCAL

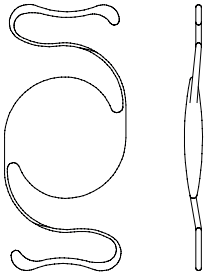
PMMA



PMMA EZE-60
INTRAOCULAR LENS

Designed to be implanted in the posterior chamber

- Foldable haptics to ease insertion
- PMMA haptics



PMMA L122UV
INTRAOCULAR LENS

Designed to be implanted in the anterior chamber

- 4-point fixation
- PMMA haptics
- White-to-white range 11.5 mm to 12.25 mm

BAUSCH + LOMB

VISCOELASTIC COHESIVE

AMVISC®

SODIUM HYALURONATE – COHESIVE VISCOELASTIC

Ref **59081L**

Contains 1.2 % Sodium Hyaluronate in physiological saline solution.

MOLECULAR WEIGHT
1 to 2.9 million Daltons

VISCOSITY AT 25°C
40,500 ± 6,000 mPa.s (at 1.0 s^{-1})
Osmolarity 320 mOsm
pH: 6.8 - 7.6

STORAGE
Between 2°C and 8°C

CONTENT & CANNULA
0.8 ml
27 G

VISCOELASTIC

COHESIVE

AMVISC®

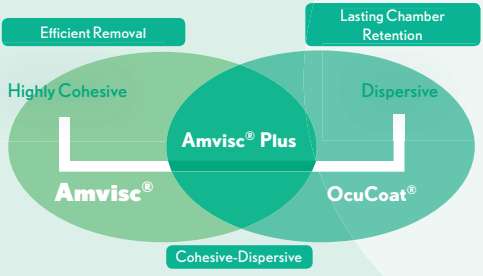
VISCOELASTIC

Amvisc® is a general purpose viscoelastic with high viscosity that provides optimal chamber maintenance. Ideal for the surgeon who performs cataract surgery using the planned extracap technique.

LENS REMOVAL

LENS IMPLANTATION

COMPLETE AND EFFICIENT REMOVAL



BAUSCH + LOMB

VISCOELASTIC

DISPERSIVE / COHESIVE

AMVISC® PLUS

SODIUM HYALURONATE DISPERSIVE/ COHESIVE VISCOELASTIC

Ref **60081L**

Contains 1.6 % Sodium Hyaluronate in physiological saline solution.

MOLECULAR WEIGHT
1 to 2.9 million Daltons

VISCOSITY AT 25°C
55,700 ± 8,200 mPa.s (at 1.0 s^{-1})
Osmolarity 340 mOsm
pH: 6.8 - 7.6

STORAGE
Between 2°C and 8°C

CONTENT & CANNULA
0.8 ml
27 G

VISCOELASTIC

DISPERSIVE / COHESIVE

AMVISC® PLUS

VISCOELASTIC

Amvisc® Plus is molecularly engineered with a versatile range of cohesion that provides lasting chamber retention plus efficient removal at the end of the case.

Cohesive versatility allows you to do what you want to do throughout the procedure, without the need for a second viscoelastic. Amvisc® Plus is the versatile viscoelastic that is ideal for every step of your surgery including MICS procedures.

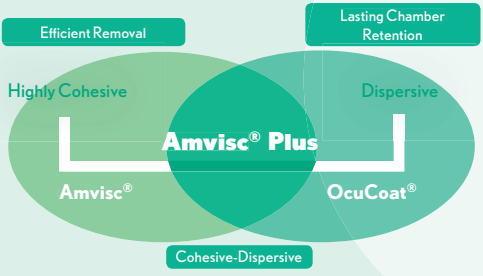
CAPSULORHEXIS

HYDRODISSECTION

LENS EXTRACTION

LENS IMPLANTATION

EASY REMOVAL



BAUSCH + LOMB

VISCOELASTIC

DISPERSIVE

OcuCoat®

HYDROXY-PROPYL-
METHYLCELLULOSE
DISPERSIVE VISCOELASTIC

Ref **CC050S / CC100SL / CC065S**

1 ml OcuCoat® contains 2% hydroxypropylmethylcellulose (HPMC) in balanced physiological saline solution.

MOLECULAR WEIGHT

≥ 80,000 Daltons

VISCOSITY AT 25°C

4,000 ± 1,500 mPa.s (at 0.0 s^{-1})
Osmolarity 285 ± 32 mOsm
pH: 7.2 ± 0.4

STORAGE

Between 2°C and 25°C

CONTENT & CANNULA

1 ml for CC050S 25 G
2 ml for CC100SL 25G
~~1 ml x 6 for CC065S 25 G~~

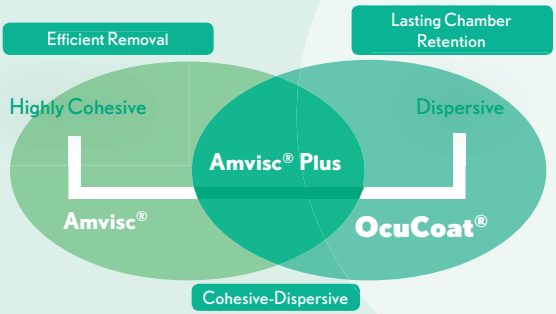
VISCOELASTIC DISPERSIVE

OcuCoat®
VISCOELASTIC

OcuCoat® is a sterile, isotonic, protein-free and dispersive viscoadherent solution for ophthalmic use.

OcuCoat® is ideal for high volume anterior segment surgery. Formulated from low molecular weight 2 % hydroxypropylmethylcellulose, OcuCoat® is a tissue protective substance with high lubrication qualities throughout the procedure.

IOL IMPLANTATION



BAUSCH + LOMB

VISCOELASTIC

SUPREME COHESIVE

EYEFILL® S.C.

SODIUM HYALURONATE SUPREME COHESIVE VISCOELASTIC

Ref **EYEFILL-SC**

Contains 2 % Sodium Hyaluronate in physiological saline solution.

MOLECULAR WEIGHT
3.2 to 3.5 million Daltons

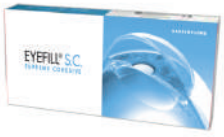
VISCOSITY AT 25°C
400,000 mPa.s (at 0.1 s^{-1})
Osmolarity 280-330 mOsmol/l
pH: 6.8 - 7.6

STORAGE
Between 2°C and 25°C

CONTENT & CANNULA
0.9 ml
25 G

VISCOELASTIC

SUPREME COHESIVE



EYEFILL® S.C.

VISCOELASTIC

EYEFILL® S.C. is a highly-viscous cohesive viscoelastic indicated in case of flat anterior chambers and iris prolapse

- Stabilizes and pressurizes the anterior chamber
- Creates a lot of space for convenient surgical intervention
- Good protection of intraocular tissues
- Very easy to remove

BAUSCH + LOMB

VISCOELASTIC COHESIVE

EYEFILL® C.

SODIUM HYALURONATE
COHESIVE VISCOELASTIC

Ref **EYEFILL-C**

Contains 1.4 % Sodium Hyaluronate in physiological saline solution.

MOLECULAR WEIGHT
3.2 to 3.5 million Daltons

VISCOSITY AT 25°C
120,000 mPa.s (at 0.1 s^{-1})
Osmolarity 280-330 mOsmol/l
pH: 6.8 - 7.6

STORAGE
Between 2°C and 8°C

CONTENT & CANNULA
1.0 ml
25 G

VISCOELASTIC COHESIVE

EYEFILL® C.
VISCOELASTIC

EYEFILL® C. is a viscous cohesive viscoelastic for standard cataract surgical procedure

- Constant stabilization of the anterior chamber and the capsular bag
- Securing of protection of the sensitive ophtalmic tissues
- Indicated in standard cataract surgery
- Easy to remove

BAUSCH + LOMB

VISCOELASTIC

DISPERSIVE / COHESIVE

EYEFILL® D.C.

SODIUM HYALURONATE
HYDROXY-PROPYL-METHYLCELLULOSE DISPERSIVE COHESIVE VISCOELASTIC

Ref **EYEFILL-DC**

Contains 1.37 % Sodium Hyaluronate and 0.57 % hydroxypropylmethylcellulose (HPMC) in physiological saline solution.

MOLECULAR WEIGHT

NaHA: 3.2 – 3.5 million Daltons
HPMC: 20,000 Daltons

VISCOSITY AT 25°C

100,000 mPa.s (at 0.1 s^{-1})
Osmolarity 270-390 mOsmol/l
pH: 6.8 - 7.6

STORAGE

Between 2°C and 8°C

CONTENT & CANNULA

1.0 ml
25 G

VISCOELASTIC

DISPERSIVE / COHESIVE

EYEFILL® D.C.
VISCOELASTIC

EYEFILL® D.C.: Dispersive Cohesive rheo-reactive viscoelastic solution

- Maintains a constant deep anterior chamber
- Protects the corneal endothelium throughout the whole cataract surgery
- Combines cohesiveness of Hyaluronic Acid with dispersive cell protective properties of HPMC
- Suitable for micro-incision cataract surgery with good tissues protection and good maintenance of the anterior chamber
- Indicated in standard cases when extra cell protection is required

BAUSCH + LOMB

VISCOELASTIC

DISPERSIVE / COHESIVE

EYEFILL® M.B.

SODIUM HYALURONATE DISPERSIVE COHESIVE VISCOELASTIC

Ref **EYEFILL-MB**

Contains 1.8 % Sodium Hyaluronate (MEGA I) + 1.4 % Sodium Hyaluronate (BIO II) in physiological saline solution.

MOLECULAR WEIGHT

3.2 to 3.5 million Daltons

VISCOSITY AT 25°C

MEGA I: 100,000 mPa.s (at 0.1 s^{-1})
BIO II: 80,000 mPa.s (at 0.1 s^{-1})
Osmolarity 280-330 mOsmol/l
pH: 6.8 - 7.6

STORAGE

Between 2°C and 8°C

CONTENT & CANNULA

MEGA I: 0.55 ml
BIO II: 0.8 ml
25 G

VISCOELASTIC

DISPERSIVE / COHESIVE

EYEFILL® M.B.

VISCOELASTIC

EYEFILL® M.B.: offers surgeons the choice between 2 viscoelastic fluids of different viscosities for all needs during cataract surgery

- Maintains constant stabilization of the anterior chamber and capsular bag
- Assures notable protection of the sensitive corneal endothelium
- 2 single-use glass syringes miscible and compatible : MEGA I (1.8% biofermentative Hyaluronic Acid) and BIO II (1.4% biofermentative Hyaluronic Acid)
- Suitable for Mini and Micro-Incision surgery (2.2 mm or less)

BAUSCH + LOMB

VISCOELASTIC

HIGH DISPERSIVE

EYEFILL® H.D.

HYDROXY-PROPYL-METHYLCELLULOSE HIGH DISPERSIVE VISCOELASTIC

Ref **EYEFILL-HD**

Contains 2.0 % hydroxypropylmethylcellulose (HPMC) in physiological saline solution.

MOLECULAR WEIGHT

86,000 Daltons

VISCOSITY AT 25°C

3,200 mPa.s (at 5 s^{-1})
Osmolarity 265-300 mOsmol/l
pH: 6.8 - 7.6

STORAGE

Between 2°C and 25°C

CONTENT & CANNULA

2.5 ml
23 G

VISCOELASTIC

HIGH DISPERSIVE

EYEFILL® H.D.

VISCOELASTIC

EYEFILL® H.D.: High Dispersive, multifunctional viscoelastic fluid

- Effective cell protection
- Prevents damage of the endothelial cells during surgery
- Useful adjuvant for funduscopy and gonioscopy
- Could be used as a coupling fluid for diagnostic and therapeutic contact lenses

BAUSCH + LOMB

VISCOELASTIC | HIGH DISPERSIVE | CORNEA PROTECTION

CORNEA PROTECT®

HYDROXY-PROPYL-METHYLCELLULOSE HIGH DISPERSIVE VISCOELASTIC

Ref **CORNEAPRO**

Contains 2 % hydroxypropylmethylcellulose (HPMC).

MOLECULAR WEIGHT

86,000 Daltons

STORAGE

Between 15°C to 25°C

CONTENT

Sterile 2 ml single-dose unit for single use (10/box)

VISCOELASTIC | HIGH DISPERSIVE | CORNEA PROTECTION

CORNEA PROTECT
HPMC 2%

CORNEA PROTECT®

VISCOELASTIC

Cornea Protect® is a sustained corneal hydration for professional use in ophthalmic surgery in single-dose unit

Optimizes the process of opthalmic procedures

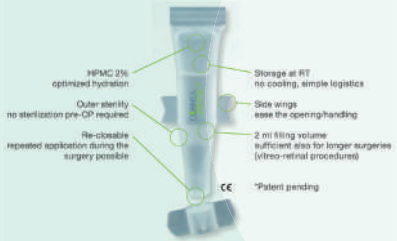
- 1 drop lasts for up to 20 min (the average duration of a cataract procedure)
- Protects the cornea 10 times longer compared to Balanced Salt Solution[1]
- Surgery without interruption, reduces the manipulations performed by the OP assistant[1]

Enhanced view

- Fast optical clarity
- Magnifying effect and crystal clear sight onto the operating field with up to 1/3 magnification

Less corneal damages after the surgery

- Reduction of post-op stipping, decreased risk of corneal lesions compared to Balanced Salt Solution
- Increased breakup time after the surgery compared to Balanced Salt Solution[1]
- Enhanced comfort for the patient during the surgery[1]



1. Chen Y-A, Hirnschall N and Findl O. Comparison of corneal wetting properties of viscous eye lubricant and balanced salt solution to maintain optical clarity during cataract surgery. Submitted to J Cataract Refract Surg. In press.

BAUSCH + LOMB

CAPSULAR TENSION RING | PMMA | PRELOADED

ACPi-11

PMMA CAPSULAR TENSION RING

Ref **ACPi-11**

MATERIAL

PMMA

Sterilization: ETO

DESIGN

One piece

Diameter: 11 mm

PRELOADED

INDICATION

- Cataract surgeries of subluxated lenses
- Zonular desinsertion
- Zonular weakness
- Risk of capsular retraction
- High myopia
- Prevention of capsular bag shrinkage in patients with congenital cataract

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ACPi-11
CAPSULAR TENSION RING

ACPi-11 ready-to-use PMMA capsular tension ring in a preloaded single-use injector system

- Repositioning of loose or desinserted zonulas in order to thwart the contraction strength of the capsular bag
- Maintains the posterior capsule taut and capsular folds can be avoided
- Time-saving system

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