

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production / Approval of Production Quality Assurance System

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Pour les dispositifs de classe IIb ou III, un certificat CE de type est requis

For class IIb or III devices, a EC type certificate is required

Fabricant / Manufacturer

HANITA LENSES

Kibbutz Hanita

2288500 ISRAEL

Catégorie du(des) dispositif(s) / Device(s) category

Système de fourniture de lentille intra-oculaire pliable utilisé pendant les interventions ophtalmologiques

Foldable Intra Ocular Lens Delivery System used during ophthalmology procedures

Voir détails sur addendum

See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000486-1-R, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T000486-1-R, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (included)



On behalf of the President

Béatrice LYS

Technical Director

Identification des dispositifs / Identification of devices

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
Injectors for IOL insertion	SoftJect 1.8 and SoftJect 2.4	Ila

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

Hanita Lenses
Kibbutz Hanita 2288500 Israel

Fabrication, contrôle final / Manufacturing, final control

GMED 0459



On behalf of the President
Béatrice LYS
Technical Director

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

HANITA LENSES

Kibbutz Hanita

2288500 ISRAEL

Catégorie du(des) dispositif(s) / Device(s) category

Lentilles Intraoculaires, anneau de tension capsulaire pliable et système de livraison de lentille intraoculaire

Intraocular lenses, capsular tension ring and Foldable Intra Ocular Lens Delivery System

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000486-1-R, T000486-2-DOCR, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T000486-1-R, T000486-2-DOCR, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (Included)


On behalf of the President
Béatrice LYS
Technical Director

GMED - 34048 rev. 2
Renouvelle le certificat 34048-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Identification des dispositifs / Identification of devices

Nom du dispositif médical <i>Medical device name</i>	Dénomination commerciale <i>Commercial designation</i>	Classe du DM <i>MD Class</i>
Intraocular Lens	OPAB 16	IIb
	OPAB 130	
	BALANCE (ABB3)	
	BAL 15	
	BAL 55	
	BAL 85	
	Blens	
	SeeLens	
	BunnyLens	
	BunnyLens Easy	
	BunnyLens/4-Lens AF	
	SeeLens AF	
	SeeLens AF EASY	
	BunnyLens AF EASY/4-Lens AF EASY	
	SeeLens MF	
	SeeLens MF EASY	
	BunnyLens MF/4-Lens MF	
	BunnyLens MF EASY / 4-Lens MF EASY	
	SeeLens HP	
	BunnyLens HP/ 4-Lens HP	
	SeeLens HP Easy	
	BunnyLens HP Easy	
	Vistor	
	Vistor EASY	
Intraocular Lens including Kits with Injector SoftJect	Intensity SL	
	Intensity BN	
	Intensity BN EZ	
	Blens KIT	
	SeeLens KIT	
	BunnyLens/4-Lens AF KIT	
	SeeLens AF KIT	
	BunnyLens AF/4-Lens AF KIT	
	SeeLens MF KIT	
	BunnyLens MF/4-Lens MF KIT	
Endo capsular Ring	SeeLens HP KIT	
	BunnyLens HP/4-Lens HP KIT	
Capsule Centering Device	Vistor and Vistor EASY KIT	
	ECR	
	ClearRing	
	AssiAnchor	



GMED 0459

**On behalf of the President
Béatrice LYS
Technical Director**

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This certificate covers the following activities and sites:

Hanita Lenses

Kibbutz Hanita 2288500 Israel

Conception, fabrication, contrôle final / Design, manufacturing, final control

GMED 0459



**On behalf of the President
Béatrice LYS
Technical Director**

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

HANITA LENSES
Kibbutz Hanita
2288500 ISRAEL

pour les activités
for the activities

Conception, fabrication et vente de lentilles de contact souples et dures, lentilles intraoculaires, anneaux de tension capsulaire. Fabrication et vente de système de livraison de lentille intraoculaire pliable

Design, manufacturing, and sales of soft and hard contact lenses, intraocular lenses, and Capsular Tension Rings. Manufacturing and sales of Foldable Intra Ocular Lens Delivery System

réalisées sur le(s) site(s) de
performed on the location(s) of

Hanita Lenses
Kibbutz Hanita 2288500 ISR

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (Included)

Etabli le / Issued on : November 26th, 2019



**CERTIFICATION
DE SYSTEMES
DE MANAGEMENT**
Accréditation n°4-0008
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr



On behalf of the President
Béatrice LYS
Technical Director

GMED N° 34047-2

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 34047-1

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

HANITA LENSES
Kibbutz Hanita
2288500 ISRAEL

pour les activités
for the activities

Conception, fabrication et vente de lentilles de contact souples et dures, lentilles intraoculaires, anneaux de tension capsulaire. Fabrication et vente de système de livraison de lentille intraoculaire pliable

Design, manufacturing, and sales of soft and hard contact lenses, intraocular lenses, and Capsular Tension Rings. Manufacturing and sales of Foldable Intra Ocular Lens Delivery System

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Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (Included)

Etabli le / Issued on : November 26th, 2019



CERTIFICATION
DE SYSTÈMES
DE MANAGEMENT
Accréditation n°4-0008
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 34047-2

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 34047-1



On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Bachelard 75015 Paris • Tél : 01 40 43 37 00 • gmed.fr



ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité/ Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

HANITA LENSES

Kibbutz Hanita

2288500 ISRAEL

Catégorie du(des) dispositif(s) / Device(s) category

Lentilles intraoculaires, anneau de tension capsulaire pliable et système de livraison de lentille intraoculaire

Intraocular lenses, capsular tension ring and Foldable Intra Ocular Lens Delivery System

Voir document complémentaire GMED / See GMED additional document

n° 38190

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001073, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001073, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : **March 17th, 2021 (included)**

Valable jusqu'au / Expiry date : **May 26th, 2024 (included)**

Digitally signed by Pereteatco Alina

Date: 2021.09.17 22:32:21 EEST



DocuSigned by:

Beatrice Lys

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On behalf of the President

Béatrice LYS

Technical Director

Ce document complémentaire GMED n° 38190 rev. 0 atteste de la validité du certificat CE n° 34048 rev. 5 au regard des informations listées ci-dessous.

This GMED additional document N° 38190 rev. 0 attests to the validity of CE certificate n° 34048 rev. 5 with regard to the information listed below.

Fabricant / Manufacturer:

**Hanita Lenses
Kibbutz Hanita
2288500 Israel**

Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessories marqués CE <i>Device designation / EC marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD Class</i>
Intraocular Lens	EXTEND SL EXTEND SL EASY EXTEND BN EXTEND BN EASY EXTEND Toric EXTEND Toric EASY OPAB 16 OPAB 130 BALANCE (ABB3) BAL 15 BAL 55 BAL 65 Blens SeeLens BunnyLens BunnyLens Easy BunnyLens/4-Lens AF SeeLens AF SeeLens AF EASY BunnyLens AF EASY/4-Lens AF EASY SeeLens MF SeeLens MF EASY BunnyLens MF/4-Lens MF BunnyLens MF EASY / 4-Lens MF EASY SeeLens HP BunnyLens HP/ 4-Lens HP	IIb

GMED 0459

GMED - 38190 rev. 0



DocuSigned by:

Beatrice Lys

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**On behalf of the President
Béatrice LYS
Technical Director**

Désignation du dispositif / Accessories marqués CE <i>Device designation / EC marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD Class</i>
Intraocular Lens	SeeLens HP Easy BunnyLens HP Easy Vistor Vistor EASY Intensity SL Intensity BN Intensity BN EZ Intensity SL HP Intensity BN HP Intensity SL HP EZ Intensity BN HP EZ VisTor MF VisTor MF Easy INTENSITY Toric INTENSITY Toric EZ INTENSITY Toric HP INTENSITY Toric HP EZ	IIb
Intraocular Lens including Kits with Injector SoftJect	Blens KIT SeeLens KIT BunnyLens/4-Lens AF KIT SeeLens AF KIT BunnyLens AF/4-Lens AF KIT SeeLens MF KIT BunnyLens MF/4-Lens MF KIT SeeLens HP KIT BunnyLens HP/4-Lens HP KIT Visitor and Vistor EASY KIT	
Endo capsular Ring	ECR CleaRing	
Capsule Centering Device	AssiAnchor	

Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
Hanita Lenses Kibbutz Hanita 2288500 Israel	Conception, fabrication, contrôle final / Design, manufacturing, final control

GMED **0459**

GMED - 38190 rev. 0



DocuSigned by:

Beatrice Lys

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On behalf of the President
Béatrice LYS
Technical Director

Mini Incision implantation

- Easy to fold and inject safely through an incision of 1.8 mm

Technical Specifications

Overall length 11 mm (9.5D and above); 11.5mm for lower D

Optic diameter 6.00 mm

Power range -10.00D – 8.00D (1.0D increments)

8.00 11.00 – 30.00 (0.5D increments)

30.00 – 35.00(1.0D increments)

Optic design Aspheric Bi convex design

Finish. Double Square Edge

Haptic angulations 5°

Material Hydrophilic Acrylic HEMA/EOEMA copolymer

with a UV and Violet Light Filter

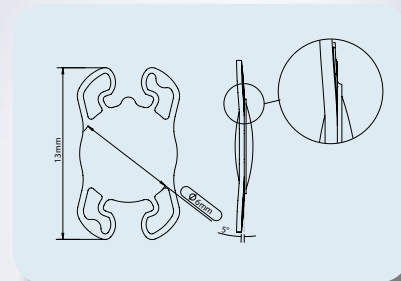
Refractive Index 1.46 (hydrated @ 35°C)

Y.A.G laser Compatible

A constant 118.9 Carl Zeiss IOL MASTER

118.56 US Biometry

Placement Capsular Bag or Sulcus



Hanita Lenses

Hanita Lenses is an Intraocular Lens and contact lenses manufacturer which is active in the Israeli domestic market and the global market since 1981.

Hanita Lenses' strategy focuses on technology and innovative R&D, in order to keep the company as a dynamic leading player in the Medical Device Ophthalmic market.

The company holds high-end technologies and vast knowledge in the refractive and cataract surgery field.

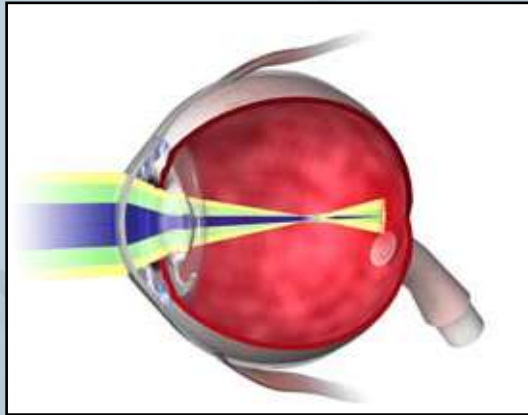
BunnyLens AF

Providing Aberration Free Vision

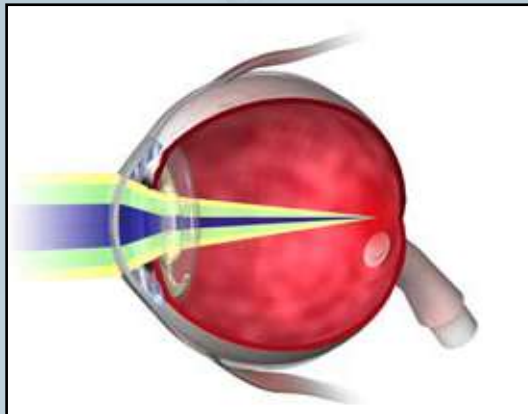
Aspheric IOL Design using mini incision technique

See for yourself

Spheric Lens
Spherical aberration



SeeLens AF
Abberation free



- **BunnyLens AF** reduces spherical aberration to minimum.
- **BunnyLens AF** improves functional vision
- **BunnyLens AF** improves night vision
- **BunnyLens AF** designed with the most advanced optical tools

BunnyLens AF, the new Aspheric Intraocular lens from Hanita Lenses, provides the patient with an excellent vision quality at day and night conditions, by using state-of-the-art aberration free aspheric optical design.

Advanced Optical Design

The aspheric BunnyLens AF was designed using the most advanced tools, by a professional R&D team of optical and mechanical engineers.

The optical profile algorithm was calculated using ZEMAX™ software – a simulating tool for optimized optical design.

Calculations were aimed in order to minimize all aberrations, including the spherical aberration of the cornea, and to optimize the MTF (Modulated Transfer Function) of the IOL.

The BunnyLens AF is thinner than ever, being easily injectable through 1.8mm incisions at even high diopters when the IOL is usually too thick.

Eye Model

Optical design was performed using Arizona eye model. This advanced model is most suitable for IOL design, since it represents the eye anatomy with relation to age.

Hanita Lenses designed an aspheric surface IOL optimized for the aged patient. Thus, the result is an advantageous accurate simulation of the visual performance of the lens in a post-operative average eye.

Geometrical Design

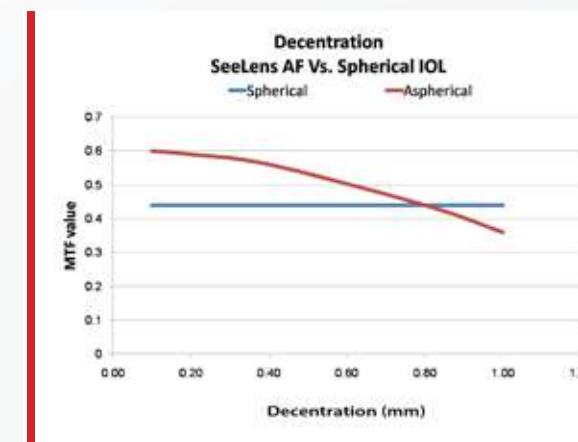
Geometrical design

- BunnyLens AF ensures excellent stability and centration due to four-point-fixated mechanical design of the haptics.
- 3600 double square edge in order to minimize PCO
- Excellent memory – slow gentle release, superior foldability

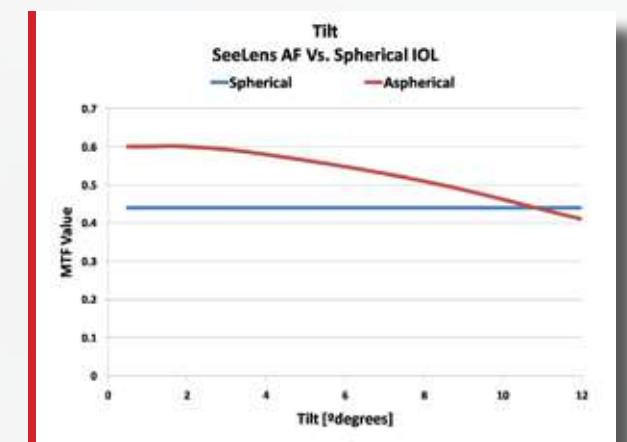
Image of the SeeLens AF square edge using SEM (X400) in a wet cell



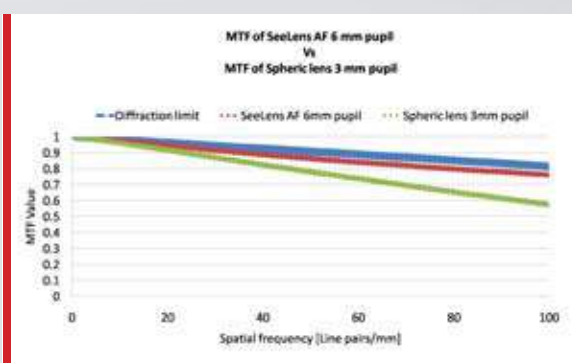
Stability and Centration



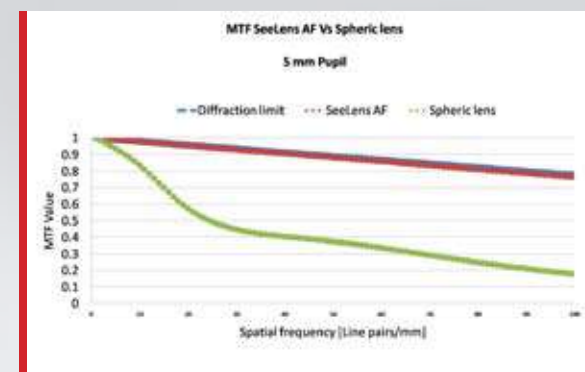
The BunnyLens AF design provides a visual advantage for patients over spherical lens even if decentered up to 0.8



The BunnyLens AF design provides a visual advantage for patients over spherical lens even if tilted up to 10 degrees



The BunnyLens AF provides excellent night vision, even better than daylight vision with a standard spherical IOL



The BunnyLens AF design provides excellent optical quality at night conditions, near the theoretical limit

Material

- The BunnyLens AF is made from hydrophilic acrylic HEMA/ EOEMA copolymer material with a UV and Violet Light Filter, having a proven excellent reputation and many years of clinical experience
- The BunnyLens AF is characterized by excellent biocompatibility and mechanical quality.

