

GMED certifies that the quality management system developed by

HANITA LENSES

**Kibbutz Hanita
2288500 ISRAEL**

Facility identifier (REPs-generated) : F005529

for the activities

**Conception, fabrication et distribution de lentilles intraoculaires, anneaux de tension capsulaire.
Fabrication et vente de système de livraison de lentille intraoculaire pliable.**

Design, manufacture and distribution of intraocular lenses, and Capsular Tension Rings. Manufacture and distribution of foldable intraocular lens delivery system.

performed on the location(s) of

See addendum

**has been audited and found to conform to the requirements of the international standard
ISO 13485 : 2016 and following regulatory requirements**

Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282

Début de validité / Effective date February 10th, 2025 (included)

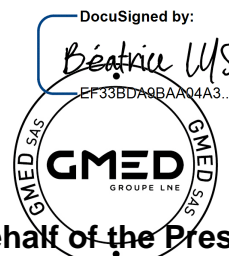
Valable jusqu'au / Expiry date : December 8th, 2027 (included)

Etabli le / Issued on : February 10th, 2025



GMED is authorised under the Medical Devices Single Audit Program
This certificate is issued according to the rules of GMED Certification
The validity of this certificate can be verified on www.gmed.fr

Modifie le certificat 38653-4



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

Ce certificat couvre les activités et les sites suivants:
This certificate covers the following activities and sites:

Hanita Lenses

Kibbutz Hanita, Israel, 2288500
Israel

Facility identifier (REPs-generated): F005529

Conception, Fabrication et Vente / Design, Manufacturing and Sales

Hanita Lenses

Horesh Haalonim 5, Ramat Ishay, Israel 3009503
Israel

Facility identifier (REPs-generated): F007763

**Emballage, stockage et envoi de lentilles intraoculaires, anneaux de tension
capsulaire et système de livraison de lentille intraoculaire pliable /
Packaging, warehousing and shipping of intraocular lenses, capsular tension rings
and foldable intraocular lens delivery system.**

Hanita Lenses

Derech Bar Yehuda 147, Ground 1 and Ground 2, Nesher Israel 3688306
Israel

Facility identifier (REPs-generated): F007762

Fabrication de Lentilles Intraoculaires (Hydrophiles) / Manufacturing of Intraocular Lenses (Hydrophilic)

Hanita Lenses – Bar-Lev

16 Bar-Lev industrial park, Misgav 2015600
Israel

Facility identifier (REPs-generated): F007764

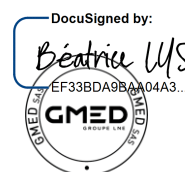
Fabrication / Manufacturing

ZHUHAI HANITA MEDICAL TECHNOLOGY Co., Ltd.
Building 6, No.129, Dingxing Road, High-tech Zone, Zhuhai
CHINA

Facility identifier (REPs-generated): F007765

Fabrication et Vente / Manufacturing and Sales

5 sites / 5 sites



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