CERTIFICATE OF REGISTRATION

N° 39279–1

GMED certifies that the quality management system developed by

MORIA S.A.

27 rue du Pied de Fourche

03160 Bourbon L'Archambault FRANCE

Facility identifier (REPs-generated) : F006200

for the activities

Conception, développement, fabrication et service après-vente d'équipements et d'instruments réutilisables ophtalmologiques. Conception, développement et fabrication d'équipements et instruments chirurgicaux, à usage unique et stériles, ophtalmologiques. (détails en addendum)

Design, Development, Manufacture and Servicing of Ophthalmic Equipment, Ophthalmic Reusable Instruments and Equipment. Design, development, Manufacture of Sterile Ophthalmic Single Use Surgical Instruments and Equipment as used in ophthalmology. (see details in addendum)

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

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
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
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité */ Effective date* **December 6th, 2023 (included)**

Valable jusqu'au */ Expiry date :* **April 16th, 2026 (included)**

Etabli le */ Issued on :* **December 6th, 2023**

GMED SAS Doc Signed by: Béatrice LYS EF33BDA9BAA04A3...

On behalf of the President

Béatrice LYS

Technical Director

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 39279-0

GMED_MDSAP2016-F-V0-07-2018

Activités couvertes par le certificat / *Activities covered by the certificate:*

French version:
Conception, développement, fabrication et service après-vente d'équipements ophtalmologiques, utilisé en ophtalmologie.
Conception, développement, fabrication et service après-vente d'équipements et instruments réutilisables ophtalmologiques, utilisé en ophtalmologie.
Conception, développement et fabrication d'équipements et instruments chirurgicaux, à usage unique et stériles, ophtalmologiques, utilisé en ophtalmologie.

English version:
Design, Development, Manufacture and Servicing of Ophthalmic Equipment as used in ophthalmology.
Design, Development, Manufacture and Servicing of Ophthalmic Reusable Instruments and Equipment as used in ophthalmology.
Design, Development, Manufacture of Sterile Ophthalmic Single Use Surgical Instruments and Equipment as used in ophthalmology.

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

- **Site A :**

  27 rue du Pied de Fourche – 03160 Bourbon L'Archambault – France
  Facility identifier (REPs-generated): F006200

  French version : Siège social – Responsable de la mise sur le marché – Fabrication – Contrôle final - Maintenance
  English version: Headquarters – legal manufacturer – Manufacturing – Final control – Servicing

- **Site B :**

  3 rue Christophe Colomb 91300 Massy – France
  23 avenue Carnot 91300 Massy – France
  Facility identifier (REPs-generated): F006201

  French version : Conception – Vente - Distribution
  English version : Design – Sales- Distribution

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2 sites / *2 facilities*

DocuSigned by:
Béatrice LYS
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director