CERTIFICATE OF REGISTRATION

N° 34933–2

GMED certifies that the quality management system developed by

MEEI BOSTON KERATOPROSTHESIS

243 Charles Street

BOSTON, MA 02114 UNITED STATES

Facility identifier (REPs-generated) : F000690

for the activities

Conception, développement, fabrication et distribution de kératoprothèses utilisées pour la chirurgie des yeux

Design, development, manufacture and distribution of keratoprosthesis devices for the area of eye surgery

performed on the location(s) of

MEEI BOSTON KERATOPROSTHESIS 243 Charles Street, Boston, MA 02114 USA

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

Canada	Medical Devices Regulations - Part 1 - SOR 98/282
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité / *Effective date* **October 1st, 2024 (included)**

Valable jusqu'au / *Expiry date :* **September 30th, 2027 (included)**

Etabli le / *Issued on :* **September 12th, 2024**

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

Renouvelle le certificat 34933-1

DocuSigned by: Beatrice LYS EF33BDA9BAA0418...

GMED SAS GMED GROUPE LNE GMED SAS

On behalf of the President

Béatrice LYS

Technical Director

GMED_MDSAP2016-F-V0-07-