

CERTIFICATE OF REGISTRATION N° 35295–6

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GMED certifies that the quality management system developed by

BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc.

8305 NW 27th Street, Suite 101 Doral, FL 33122 UNITED STATES

Facility identifier (REPs-generated): F002750

for the activities

Conception, développement, fabrication, et distribution d'inserts cornéens qui incorporent la membrane amniotique dans le domaine de l'ophtalmologie

Design, development, manufacture, and distribution of corneal inserts that incorporate the amniotic membrane for the area of ophtalmology

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

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

Début de validité / Effective date October 3rd, 2023 (included)
Valable jusqu'au / Expiry date :September 24th, 2026 (included)
Etabli le / Issued on : October 3rd, 2023



On behalf of the President
Béatrice LYS
Technical Director

Béatriu LUS

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 35295-5



Addendum au certificat n° 35295 rev. 6 page 1/1 Addendum of the certificate n° 35295 rev. 6 Dossier / File N° T001727 P1-R

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc

8305 NW 27th Street, Suite 101 Doral, FL 33122 USA

Conception, fabrication et distribution

Design, manufacturing and distribution

BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc

7300 Corporate Center Dr., Suite 700 Miami, FL 33126 USA

Service à la clientèle

Customer Service

BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc

7235 Corporate Center Drive, Suite B Miami, FL 33126 USA

Recherche et développement

Research and Development

BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc

7000 SW 97th Ave. Suites 211, 212 and 118 Miami, FL 33173 USA

Fabrication

Manufacturing

4 sites / 4 sites



On behalf of the President
Béatrice LYS
Technical Director