

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 ophthalmology

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 807 - -Subparts A to D

Début de validité / Effective date March 16th, 2023 (included)

Valable jusqu'au / Expiry date : March 24th, 2025 (included)

Etabli le / Issued on : March 16th, 2023



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 35295-4



DocuSigned by:

Béatrice LYS

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**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 :

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



DocuSigned by:
Béatrice LYS
EF33BD9BA04A3...

On behalf of the President
Béatrice LYS
Technical Director