

**GMED certifie que le système de management de la qualité développé par**  
*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**

**pour les activités**  
*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*

**réalisées sur le(s) site(s) de**  
*performed on the location(s) of*

**BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc.  
8305 NW 27th Street, Suite 101 Doral, FL 33122 - USA**

**BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc.  
7300 Corporate Center Dr., Suite 700 Miami, FL 33126 - USA**

**BioTissue Holdings Inc. also DBA BioTissue Ocular Inc. also DBA BioTissue Surgical Inc.  
7235 Corporate Center Drive, Suite B Miami, FL 33126 - USA**

**est conforme aux exigences des normes internationales**  
*complies with the requirements of the international standards*

**ISO 13485:2016**

**Début de validité / Effective date November 15th, 2024 (included)**

**Valable jusqu'au / Expiry date : September 24th, 2026 (included)**

**Etabli le / Issued on : November 15th, 2024**



Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

DocuSigned by:  
*Béatrice LYS*  
EF33B9A9BA04A3  
**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**



GMED N° 33435-6

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Modifie le certificat 33435-5

**GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459**  
**Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • [gmed.fr](http://gmed.fr)**

**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*

\*\*\*\*\*

**3 sites / 3 sites**

DocuSigned by:  
*Béatrice LYS*  
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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**