

GMED certifies that the quality management system developed by
Tissuetech, Inc. also doing business as Bio-Tissue, Inc. also doing business as
Amnio Medical, 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

Tissuetech, Inc. 8305 NW 27th Street, Suite 101 Doral, FL 33122 USA
Tissuetech, Inc. 7300 Corporate Center Dr. Ste. 700 Miami, FL 33126 USA
Tissuetech, Inc. 7235 Corporate Center Drive, Ste. B Miami, FL 33126 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 March 25th, 2022 (included)

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

Etabli le / Issued on : March 22nd, 2022



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 35295-3



DocuSigned by:

US Béatrice
 EF33BDA9BAA04A3...

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 :

Tissuetech, Inc.

also doing business as Bio-Tissue, Inc.
also doing business as Amniox Medical, Inc.

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

Conception, fabrication et distribution
Design, manufacturing and distribution

Tissuetech, Inc.

also doing business as Bio-Tissue, Inc.
also doing business as Amniox Medical, Inc.

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

Service à la clientèle
Customer Service

Tissuetech, Inc.

also doing business as Bio-Tissue, Inc.
also doing business as Amniox Medical, Inc.

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

Recherche et développement
Research and Development

3 sites / 3 sites



DocuSigned by:

LYS Béatrice
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director