

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

7300 Corporate Center Dr., Ste 700
Miami, FL 33126 United States

D.U.N.S. identification number : 069979900

for the activities

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

Design and development and manufacture of corneal inserts that incorporate the amniotic membrane for the area of ophthalmology

performed on the location of

Tissue Tech, Inc.
7300 Corporate Center Dr., Ste 700, 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, 2019 (included)

Valable jusqu'au / Expiry date : March 24th, 2022 (included)

Etabli le / Issued on : March 25th, 2019



Lionel DREUX
Certification Director



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

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

Tissuetech, Inc.

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

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

Siège social et service à la clientèle
Headquarters and Customer Service

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

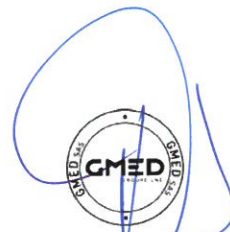
Tissuetech, Inc. (DUNS 80-628-4191)

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

11315 Rancho Bernardo Road, suite 140/141
San Diego, CA 92127 USA

Entreposage, étapes finales d'emballage et distribution de tissus biologiques
Storage, final packaging, labelling and delivery of biological tissues

3 sites / 3 sites



Lionel DREUX
Certification Director