CERTIFICATE OF REGISTRATION

N° 34445–5

GMED certifies that the quality management system developed by

TeDan Surgical Innovations, Inc.
12320 Cardinal Meadow Drive, Suite 150
Sugar Land, TX 77478 UNITED STATES

Facility identifier (REPs-generated) : F000696

for the activities

Conception, fabrication et distribution de systèmes d'écarteurs chirurgicaux, instruments et accessoires pour chirurgies en neurologie, orthopédie, du rachis et du coeur

Design, manufacture and distribution of surgical retractor systems, instruments and accessories for neurological, orthopedic, spine and heart surgery

performed on the location(s) of

TeDan Surgical Innovations, Inc. 12320 Cardinal Meadow Drive, Suite 150 Sugar Land, TX 77478 USA

has been audited and found to conform to the requirements of the international standard ISO 13485 : 2016 and following regulatory requirements

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 Production Quality assurance Procedure
Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité */ Effective date* **June 20th, 2024 (included)**
Valable jusqu'au */ Expiry date :* **June 19th, 2027 (included)**
Etabli le */ Issued on :* **June 10th, 2024**

DocuSigned by: Béatrice LYS EF33BDA9BAA04A0...

GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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 34445-4

GMED_MDSAP2016-F-V0-07-