CERTIFICATE OF REGISTRATION

N° 36596–2

GMED certifies that the quality management system developed by

DxTx Medical, Inc.
639 Alpha Drive
Pittsburgh, PA 15238 UNITED STATES

Facility identifier (REPs-generated) : F004442

for the activities

Conception, développement, fabrication et distribution de sondes spiralées endo-rectales IRM et d'interfaces pour le domaine de l'imagerie et de ballonnets endo-rectaux.

Design, development, manufacture and distribution of MRI endo-rectal coil probes and interfaces for the area of imaging, and endo-rectal balloons.

performed on the location(s) of

DxTx Medical, Inc. 639 Alpha Drive, Pittsburgh, PA 15238 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 1 (excluding Part 1.6) - Full 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
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité / *Effective date* **March 12th, 2023 (included)**
Valable jusqu'au / *Expiry date :* **March 11th, 2026 (included)**
Etabli le / *Issued on :* **March 3rd, 2023**

DocuSigned by:
Béatrice LYS
EF33BDA9BA...

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 36596-1

GMED_MDSAP2016-F-V0-07-