

*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, 2026 (included)**

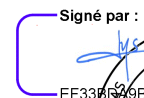
**Valable jusqu'au / Expiry date : March 11th, 2029 (included)**

**Etabli le / Issued on : January 16th, 2026**



GMED is recognised 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.lne-gmed.com](http://www.lne-gmed.com).

Renouvelle le certificat 36596-2

Signé par :  
  
EF335529BAA04A3...  
  
**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**