

GMED certifies that the quality management system developed by

DxTx Medical, Inc.

639 Alpha Drive

Pittsburgh, PA 15238 UNITED STATES

D.U.N.S. identification number :082448484

for the activities

Conception, développement, fabrication et distribution de sondes d'IRM à bobine endorectale et d'interfaces pour le domaine de l'imagerie

The design, development, manufacture and distribution of MRI endo-rectal coil probes and interfaces for the area of imaging

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
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

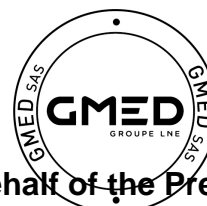
Début de validité / Effective date March 12th, 2020 (included)

Valable jusqu'au / Expiry date :March 11th, 2023 (included)

Etabli le / Issued on : March 12th, 2020



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



On behalf of the President

Béatrice LYS

Technical Director

DocuSigned by:

Beatrice Lys

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