CERTIFICATE OF REGISTRATION

N° 38731–0

GMED certifies that the quality management system developed by

CenterPoint Systems LLC.

3338 Parkway Blvd,

West Valley City, UTAH 84119 UNITED STATES

Facility identifier (REPs-generated) : F005828

for the activities

Conception et développement, fabrication et distribution de cathéters et de gaines dans la zone cardiovasculaire.

Design and development, manufacture, and distribution of catheters and sheaths for the areas of cardiovascular.

performed on the location(s) of

CenterPoint Systems LLC. 3338 Parkway Blvd, West Valley City, UTAH 84119 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. 16/2013 RDC ANVISA n. 23/2012 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* **December 29th, 2021 (included)**

Valable jusqu'au / *Expiry date :* **December 28th, 2024 (included)**

Etabli le / *Issued on :* **December 29th, 2021**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President

Béatrice LYS

Technical 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

GMED_MDSAP2016-F-V0-07-