

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 gaines d'accès utilisés dans les domaines cardiovasculaire, de gastro-entérologie et urologie.

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

performed on the location(s) of

**CenterPoint Systems LLC. 3338 Parkway Blvd, West Valley City, UTAH 84119 USA
CenterPoint Systems LLC. 2187 Printers Row, Unit #101, 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. 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 January 9th, 2025 (included)

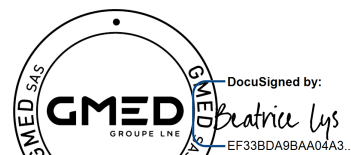
Valable jusqu'au / Expiry date :December 28th, 2027 (included)

Etabli le / Issued on : January 9th, 2025



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 38731-1



**On behalf of the President
Béatrice LYS
Technical Director**

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

CenterPoint Systems LLC.
3338 Parkway Blvd,
West Valley City, UT 84119, USA

Siège social, conception, fabrication et contrôle final


Headquarters, design, manufacturing and final control

CenterPoint Systems LLC.
2187 Printers Row, Unit #101,
West Valley City, UT 84119, USA

Stockage et expédition de produits finis, et contrôle qualité

Warehousing and shipping of finished goods, and quality inspection

2 sites / 2 sites

 DocuSigned by:
Béatrice Lys
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**On behalf of the President
Béatrice LYS
Technical Director**