



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C726480

Initial certification date:
2024-12-23

Expiry Date:
2027-12-22

This is to certify that the management system of

CenterPoint Systems, LLC

3338 Parkway Blvd, West Valley City, UT, 84119, USA

F007711

and the sites as mentioned in the appendix accompanying this certificate
has been found to conform to the Quality Management System standard:

**ISO 13485:2016 and the requirements of the following regulatory
authorities**

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(excluding Part 1.6) – Full Quality Assurance Procedure

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 820

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

This certificate is valid for the following scope:

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

Place
Høvik

Effective Date:
2024-12-23



DNV is an MDSAP
Recognized Auditing Organization



For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Tone Kolpus

Tone Kolpus
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/>, with the certificate number/manufacturer name.



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Appendix to Certificate

Locations included in the certification are as follows:

CenterPoint Systems F007711	3338 Parkway Blvd, West Vally City, UT, 84119, USA	Design and development, manufacture, and distribution of catheters and sheaths for the area of cardiovascular, gastroenterology, and urology.
CenterPoint Systems F007711	2187 Printers Row, West Valley City, UT, 84119, USA	Warehousing and shipping of finished goods, quality inspection.

