

EU Quality Management System Certificate

Certificate no.:
C650471

Initial certification date:
23 May 2025

Valid Until:
22 May 2030

This is to certify that the quality system of

CenterPoint Systems, LLC

3338 Parkway Blvd, West Valley City, UT, 84119

SRN: US-MF-000009054

For design, production, and final product inspection/testing of:

Design, Production and final inspection/testing of sterile catheters and sterile Helix Locking tool.

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX,
(Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:
Høvik, 28.01.2026



For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway



Menaka Singh
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	3016082	23 May 2025
1.0	Addition of SSPC Catheter	3215368	28 Jan 2026

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
CPS Locator 3D Delivery Catheter The CPS Locator 3D Delivery Catheter is indicated for the venous introduction of pacing or defibrillator leads.	CPS Locator 3D Delivery Catheter DS2C100-42, DS2C200-42, DS2C300-42, DS2C200-45, DS2C300-45	III
SSPC Delivery Catheter The SSPC and SSPC NXT Delivery Catheter is intended for venous introduction of pacing or defibrillator leads.	SSPC Delivery Catheter and SSPC NXT Delivery Catheter	III
Helix Locking Tool	Helix Locking Tool 5616	Is

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: C744077 and C835165

The complete list of devices is filed with the Notified Body

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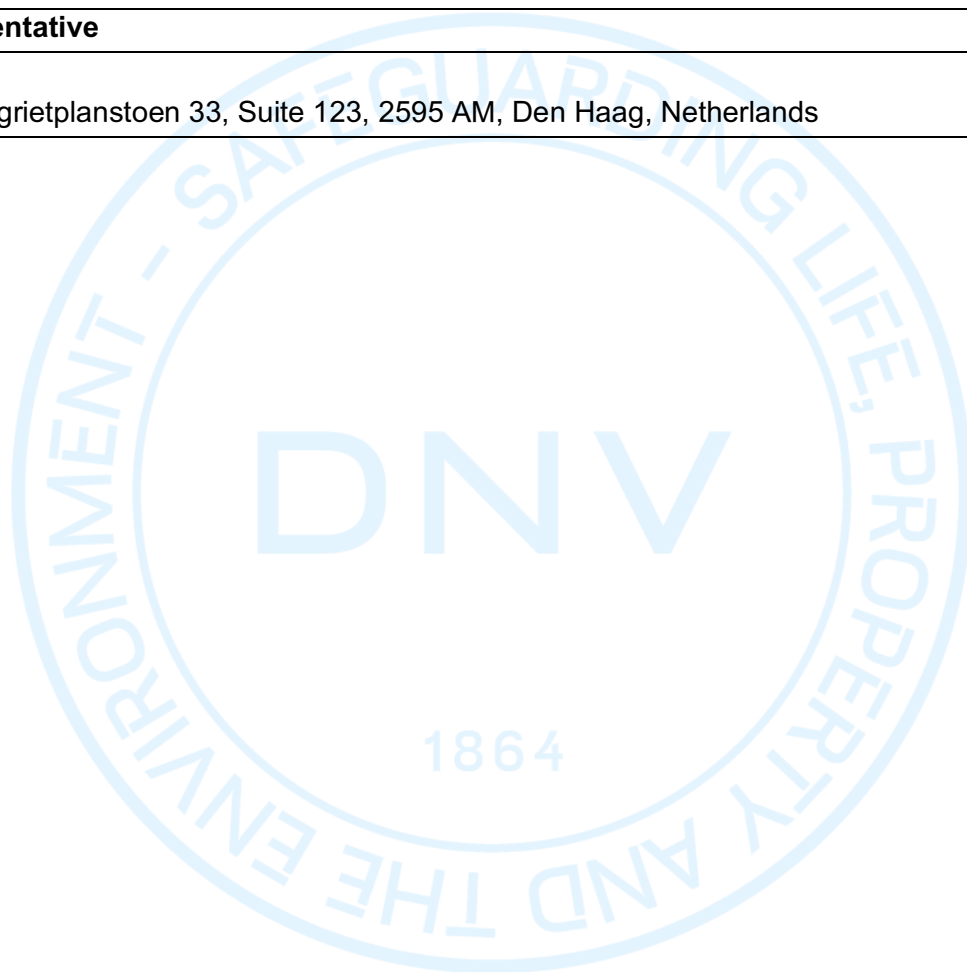
Sites covered by this certificate

Site Name	Address
CenterPoint Systems	3338 Parkway Blvd, West Valley City, UT 84119

EU Representative

MedEnvoy

Prinses Margrietplanstoen 33, Suite 123, 2595 AM, Den Haag, Netherlands



Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.