



EU Quality Management System Certificate

Certificate no.:
C608701

Initial certification date:
24 September 2025

Valid Until:
23 September 2030

This is to certify that the quality system of

CYBER SURGERY S.L.

PASEO MIKELETEGI 71 3º LOCAL 336,

20009 Donostia – San Sebastián (Gipuzkoa), Spain

SRN: ES-MF-000042958

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

Robotic surgery devices including software

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, 24 September 2025



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

Palani Damodharan
Management Representative

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

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

MDR-CO-078-A V0.8



DNV

Certificate no.: C608701
Place and date: Høvik, 24 September 2025

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	2905983	24 September 2025

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Cyber Surgery Spine Robotic Assistant – Cyber Surgery Spine Robotic Assistant is a robotic assistant designed to be used on transpedicular screw planification for spinal fusion. The system guides the surgeon and facilitates the surgical procedure.	Cyber Surgery Spine Robotic Assistant	IIb
The Cyber Surgery Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform invasive steps of the clinical procedures.	Cyber Surgery Spine Bone Clamps	IIa
The Cyber Surgery Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform invasive steps of the clinical procedures.	Cyber Surgery Spine Dilator	IIa
The Cyber Surgery Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform invasive steps of the clinical procedures.	Cyber Surgery Spine Awl	IIa
The Cyber Surgery Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform invasive steps of the clinical procedures.	Cyber Surgery Spine Drill Guide	IIa
The Cyber Surgery Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform invasive	Cyber Surgery Spine K-Wire adapter	IIa

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steps of the clinical procedures.		
The Cyber Surgery Spine Fiducial - is a single-use, sterile (gamma radiation). The Cyber Surgery Spine Fiducial is intended for use with Cyber Surgery Spine Robotic Assistant as an aid during image registration process to perform the recording of the patient's position by intraoperative imaging.	Cyber Surgery Spine Fiducial	Is
The Cyber Surgery Non-Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform non-invasive steps of the clinical procedures.	Cyber Surgery Spine AB Tool Guide	Ir
The Cyber Surgery Non-Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform non-invasive steps of the clinical procedures.	Cyber Surgery Spine C Tool Guide	Ir
The Cyber Surgery Non-Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform non-invasive steps of the clinical procedures.	Cyber Surgery Spine Surgical Cover Tool	Ir
The Cyber Surgery Non-Invasive Surgical Instruments are reusable surgical instruments intended for use with Cyber Surgery Spine Robotic Assistant during the spinal surgery to perform non-invasive steps of the clinical procedures.	Cyber Surgery Spine Tool Guide Adapter	Ir

* 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.: NA

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
CYBER SURGERY S.L.	PASEO MIKELETEGI 71 3º LOCAL 336, 20009 Donostia – San Sebastián (Gipuzkoa), Spain

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.