EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
C576271	30 August 2024	29 August 2029

This is to certify that the quality system of

Otivio AS

Drammensveien 130, 0277 Oslo, Norway

SRN: NO-MF-000007971

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

Devices for stimulation FlowOx™ Blood Flow Enhancement System.

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, 30 August 2024

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.

Certificate no.: C576271
Place and date: Høvik, 30 August 2024

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2806379	30 August 2024

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class
Blood Flow Enhancement System	FlowO$_X$™ 2.0	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Otivio AS - HQ	Drammensveien 130, 0277 Oslo, Norway

EU Representative
N/A

Certificate no.: C576271
Place and date: Høvik, 30 August 2024

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 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.