EU Quality Management System Certificate FI25/00000050

The quality management system of

Marginum Oy

Marginum Oy, Hermiankatu 6-8, FI-33720 Tampere, Finland SRN: FI-MF-000030256

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I and III)

for the following:
Medical devices intended for optical tissue monitoring used in fluorescence-guided neurosurgery

Issue 2
Previous certificate's number and issue: FI25/00000050, Issue 1
Change in between this certificate and the previous one: Address change

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 1 July 2026 until 16 September 2027 and remains valid subject to satisfactory surveillance audits.
Certified since 17 September 2025
Certified activities performed by additional sites are listed on the subsequent pages.

Authorised by
Jani Högman, Certifier

SGS FIMKO OY
Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 - www.sgs.fi - Business ID 0634247-4

Marginum Oy

Regulation (EU) 2017/745 Annex IX (I and III)

Issue 2
Sites
Marginum Oy, Hermiankatu 6-8, FI-33720 Tampere, Finland Medical devices intended for optical tissue monitoring used in fluorescence-guided neurosurgery

Marginum Oy

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 2

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIb
MDA 0204, MDS 1009, MDS1010, MDS 1014, MDT 2010, MDT 2011
EMDN Z12109099 various neurology and neurosurgery instruments - other
Aspirate Tissue Detector HIVEN, Basic UDI-DI 64298109943000X8
HIVEN device is intended for tissue fluorescence detection during fluorescence-guided surgical operations for suspected high-grade gliomas in which 5-aminolevulinic acid (5-ALA) is used. The device is used for detecting fluorescence of flowing tissues within a transparent tube and providing auditory feedback of tissue fluorescence for neurosurgeons. There is no patient contact intended with this device.

The certification decision is based on the following:

Report Identification and Date:
FPMDREG1007- MDR Notification of QMS Changes and Regulatory Actions vK _Marginum OY address change after 2026-07-01 _JHÖ

Applied Standards / Common specifications:
EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021, references to other relevant CS and harmonized standards are in the reports

Conditions for or limitation to the validity of the certificate:
The certificate is limited for the indication of malignant glioma surgery in adult patient group.

EU Authorised Representative:
N/A, the manufacturer is in the EU