EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
7229GB448240322	7229AU10F	2024-03-22	2027-07-15

This is to certify that the quality system of

Luciole Medical AG

Baslerstr. 30, 8048 Zürich, Switzerland

SRN: CH-MF-000015856

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

Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

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

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-03-22

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Markus Bianchi
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.820111 EN Rev. 5 2023.11.28

Certificate no.: 7229GB448240322
Place and date: Hamburg, 2024-03-22

Sites covered by this certificate

Luciole Medical AG, Baslerstr. 30, 8048 Zürich, Switzerland

Authorised representative

Veranex Germany GmbH, Landsbergerstr. 302, 80687 München, Germany
SRN: DE-AR-000005578

Certificate no.: 7229GB448240322
Place and date: Hamburg, 2024-03-22

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0203	Z12109006	Brain tissue monitoring systems
MDA 0315	Z12109006	Brain tissue monitoring systems

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDN 1201	Non-active non-implantable devices for anaesthesia, emergency and intensive care