

MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 7229GB445230731

Final assessment report no. 7229AU09F

Effective date

Expiry date 2025-07-15

This is to certify that

Luciole Medical AG

Baslerstr. 30, 8048 Zürich, Switzerland

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date Hamburg, 2023-07-31



For the issuing office DNV MEDCERT GmbH 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 info@medcert.de

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

820115 EN Rev 1 2022.10.17



Certificate no.: 7229GB445230731 Place and date: Hamburg, 2023-07-31

Sites covered by this certificate

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

Activities and products/services covered by this certificate

Design and development, manufacture, final inspection, and distribution of

- Devices for monitoring of cerebral parameters
- Probes for monitoring of cerebral parameters

