

MANAGEMENT SYSTEM CERTIFICATE

Certificate no
7229GB452251202

Final assessment report no.
7229AU12F

Effective date
2025-12-02

Expiry date
2028-07-15

This is to certify that

Luciole Medical AG

Baslerstrasse 30, 8048 Zürich, Switzerland

has introduced, applies and maintains a management system at the site listed on the following page.

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

EN ISO 13485:2016 + AC:2018 + A11:2021

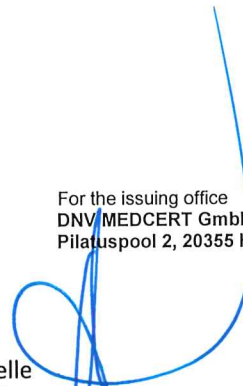
This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2025-12-02

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00



Markus Bianchi
Certification Body Operations

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



DNV

Certificate no.: 7229GB452251202
Place and date: Hamburg, 2025-12-02

Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of

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

