DNV

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

NOTIFIED BODY 0482: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

DNV

EU Technical Documentation Assessment Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
13560GB450240322	13560AU08F	2024-03-22	2029-03-21

This is to certify that

Medical devices listed on the following pages

Manufactured by

Luciole Medical AG

Baslerstr. 30, 8048 Zürich, Switzerland

SRN: CH-MF-000015856

Have been assessed and found to comply with respect to

Technical Documentation Assessment as described in Annex IX, Chapter II 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 certificate assumes that DNV MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by DNV MEDCERT.

For conditions or for limitations to the validity refer to the relevant final assessment report. Examinations and tests performed, e. g. reference to relevant common specifications, harmonised standards, test reports and audit report(s), are recorded in the relevant reports. For placing on the market of the medical devices covered by this certificate, an additional EU Quality Management System Certificate according to Annex IX Chapter I of Regulation (EU) 2017/745 is required.

Place and date
Hamburg, 2024-03-22

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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