CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

No. G11DK 136906 0002 Rev. 00

Manufacturer:

CustomSurg AG
Bubenbergstrasse 1
8045 Zurich
SWITZERLAND

SRN Manufacturer - CH-MF-000050675

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.
Details on devices covered by the quality management system are described on the following page(s). The Report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

If class IIa or class IIb devices are covered by this certificate, The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes a further assessment of the technical documentation on the basis of representative samples.

If class Is or class Im devices are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions, or conformity of the devices with the metrological requirements.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11DK 136906 0002 Rev. 00

Report No.: MEDICI/DK-IC-QS/2026/09259

Valid from: 2026-06-11
Valid until: 2031-06-10

Malou Hjæresen
Head of Notified Body

Issue date: 2026-06-11

TÜV SÜD Danmark ApS, Johanne Møllers Passage 1, 3rd floor, 1799 Copenhagen V, Denmark,
is Notified Body with identification no. 2443

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

No. G11DK 136906 0002 Rev. 00

Device(s) covered by this Certificate:

Risk Classification: Class IIa

Device Group Description:

MDA 0315 - Medical Device Software

The validity of this certificate depends on conditions and/or is limited to the following: None

Revision History:

Rev.	Dated	Report	Description
00	2026-06-11	MEDICI/DK-IC-QS/2026/09259	Initial issuance

TÜV SÜD Danmark ApS, Johanne Møllers Passage 1, 3rd floor, 1799 Copenhagen V, Denmark, is Notified Body with identification no. 2443