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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Certificate

No. Q5 015735 0028 Rev. 03

Holder of Certificate: **Sedatelec**
Chemin des Mûriers
69540 Irigny
FRANCE

Facility(ies): **Sedatelec**
Chemin des Mûriers, 69540 Irigny, FRANCE

Design and development, production and distribution of sterile medical needles, medical lasers, skin, nerves and muscles stimulators

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of sterile medical needles, medical lasers, skin, nerves and muscles stimulators**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 015735 0028 Rev. 03

Report No.: 713415147

Valid from: 2026-12-13
Valid until: 2029-12-12

Date, 2026-11-10

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany