ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 076875 0017 Rev. 03

Holder of Certificate: **SURGIKA S.r.l.**
Via 2 Giugno 125
52021 LEVANE - BUCINE (AR)
ITALY

Facility(ies): **SURGIKA S.r.l.**
Via 2 Giugno 125, 52021 LEVANE - BUCINE (AR), ITALY

See scope of certificate

Certification Mark:

Scope of Certificate: **Design, manufacture and distribution of single use medical devices: Sterile procedural packs for operating room, clinic and ward; Sterile disposable surgical instruments; Sterile medical devices for infusion management; Sterile and not sterile medical devices in non-woven and synthetic materials for operating room and for clinical procedures.**

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 076875 0017 Rev. 03

Report No.: ITA200220004495

Valid from: 2025-03-30
Valid until: 2028-03-29

Date, 2025-02-24

Christoph Dicks
Head of Certification/Notified Body

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