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

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

Product Service

Certificate

No. Q5 104088 0002 Rev. 02

Holder of Certificate:

AMES MEDICAL PROSTHETIC SOLUTIONS S.A.U.
Cami Can Ubach 8
Barcelona
08620 St. Vicenc dels Horts
SPAIN

Facility(ies):

AMES MEDICAL PROSTHETIC SOLUTIONS S.A.U.
Cami Can Ubach 8, Barcelona, 08620 St. Vicenc dels Horts, SPAIN

See Scope of Certificate

Certification Mark:

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

Scope of Certificate:

Design, development, manufacturing and sales of sterile porous implants for implantation in the extremities, and related sterile and non-sterile surgical instruments.

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 104088 0002 Rev. 02

Report No.: ITA200220007953

Valid from: 2026-03-05
Valid until: 2029-03-04

Date, 2025-09-11

Christoph Dicks
Head of Certification/Notified Body

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