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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 104088 0004 Rev. 00

Manufacturer:

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

SRN Manufacturer - ES-MF-000000663

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 104088 0004 Rev. 00

Report No.: ITA2011726

Valid from: 2024-07-24
Valid until: 2029-07-23

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-07-24

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIb
Device Group:	P091299 - OSTEOSYNTHESIS DEVICES, DEVICES FOR TENDON AND LIGAMENT SYNTHESIS - OTHER
Intended Purpose:	Implantable wedges for correction of foot deformities
Classification:	Class IIa
Device Group:	P091399 - ORTHOPAEDIC IMPLANT INSTRUMENTS, SINGLE-USE - OTHER
Intended Purpose:	\
The validity of this certificate depends on conditions and/or is limited to the following:	\

Revision History:

Rev.	Dated	Report	Description
00	2024-07-24	ITA2011726	Initial issuance

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