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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104088 0001 Rev. 00

Manufacturer:

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

Product Category(ies): **Implantable wedges for the correction of foot deformities and related single-use accessories (sizers, tweezers, impactors)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1160448

Valid from: 2020-03-05
Valid until: 2024-05-26

Date, 2020-03-05

Christoph Dicks
Head of Certification/Notified Body

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

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