



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ASTROLABE - Fabricação de Implantes

Médicos, Lda

Rua dos Caniços Nº34

Vialonga

Vila Franca de Xira

2625-253 Portugal

Facility ID Number: F007966

Holds Certificate No: MDSAP 822733

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

The design and manufacture of end-user sterilised implantable bone plates, bone screws, wires, bone staples, hooks and washers for use in upper and lower extremities and limbs, including their associated instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-07-01 Effective Date: 2025-07-01 Expiry Date: 2028-06-30

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."