EU Quality Management System Certificate ES25/00000301

The management system of

Albino Dias de Andrade, S.A.

Rotunda do Complexo Desportivo, 15 Seroa, 4595-069 Paços de Ferreira, Porto - Portugal

SRN Number: PT-MF-000002823

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 20 May 2025 until 13 March 2030 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 13 September 2029

Issue 3. Certified since 13 March 2025

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
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Albino Dias de Andrade, S.A.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class Is devices:
MDS1005
Sterile Bandages and Dressings.
[Basic UDI-DI: 560082989B0201X5, 560082989B0202X7, 560082989B0203X9, 560082989B0204XB, 560082989B0205XD, 560082989B0206XF, 560082989B0207XH, 560082989B0101WY]

Class IIa devices:
MDN1204
Non-sterile Gauze and non-woven dressings.
[Basic UDI-DI: 560082989C0101XB]
Non-sterile Gauze and non-woven dressings with X-ray thread.
[Basic UDI-DI: 560082989C0103XF]

MDN1204, MDS1005
Sterile Gauze and non-woven dressings.
[Basic UDI-DI: 560082989C0102XD]
Sterile Gauze and non-woven dressings with X-ray thread.
[Basic UDI-DI: 560082989C0104XH]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

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Certification is based on following reports: - ES/MAD/226345 - S2A 1.1 + TFR 1.2 + TFR 1.3 + CTC
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: Update class Is ' Sterile Bandages' to 'Sterile Bandages and Dressings' and add basic UDI-DI's: 560082989B0207XH and 560082989B0101WY.

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