

EU Quality Management System Certificate ES26/00000069

The management system of

AGU-PUNT, S.L.

C/ Casp 158, Local. 08013. Barcelona, Spain
SRN Number: ES-MF-000033629

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 26 January 2026 until 26 January 2031 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 26 July 2030

Issue 1. Certified since 26 January 2026



Authorised by

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Compliance

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EU Quality Management System Certificate ES26/00000069,
continued

AGU-PUNT, S.L.

SGS

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

Class IIa devices:

MDA0305, MDS1009

Intratissue percutaneous electrolysis system for application of physiotherapy techniques. Model: APSe4.

Basic UDI-DI: 8437016482APSe4*CM

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

Certification is based on following reports: - ES/BCN/300002729 - S2A 1.1 + TFR 1.7

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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