



# EU Quality Management System Certificate ES26/00000165

The management system of

## FAMADENT S.L.U. (PROTECHNO ®)

Pol. Ind. Empordà Internacional, C/ Garrotxa, 6, 17469 Vilamalla, Girona, Spain  
SRN Number: ES-MF-000000270

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 16 February 2026 until 16 February 2031 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 16 August 2030

Issue 1. Certified since 16 February 2026

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Authorised by  
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EU Quality Management System Certificate ES26/00000165,  
continued

**FAMADENT S.L.U. (PROTECHNO ®)**

**SGS**

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

Class IIa devices:

MDN1209

Methyl-methacrylate polymers for the manufacture of dental prosthesis (denture bases and orthodontic plates):

- ECO-CRYL HOT: Heat-polymerizable polymer for total and partial denture bases manufacturing.
- ECO-CRYL M: Microwave cured polymer for total and partial denture bases manufacturing.
- ECO-CRYL COLD: Autopolymerizable polymer for reparation and relining of denture plates.
- ECO-CRYL PRO: Autopolymerizable pour-type polymer for total and partial denture bases manufacturing.
- TECHNO SIN: Autopolymerizable polymer for orthodontic plates manufacturing

[Basic UDI-DI: 84354577-00014U]

Spanish translation:

Dispositivos de clase IIa:

MDN1209

Polímeros de metacrilato de metilo para la fabricación de prótesis dentales (bases de dentaduras y placas ortodónticas):

- ECO-CRYL HOT: Polímero termopolimerizable para la fabricación de bases de prótesis dentales totales y parciales.
- ECO-CRYL M: Polímero curado por microondas para la fabricación de bases de prótesis dentales totales y parciales.
- ECO-CRYL COLD: Polímero autopolimerizable para la reparación y rebasado de placas protésicas dentales.
- ECO-CRYL PRO: Polímero autopolimerizable por técnica de vertido para la fabricación de bases de prótesis dentales totales y parciales.
- TECHNO SIN: Polímero autopolimerizable para la fabricación de placas ortodónticas.

[UDI-DI básico: 84354577-00014U]

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](mailto:NB1639@sgs.com).

Limitation N/A

Certification is based on following reports: - ES/BCN/300007405 - S2A 1.2 + TFR 1.3

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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**Sites**

FAMADENT S.L.U. (PROTECHNO ®)

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