

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 780351 R000

**Manufacturer:** GMI Dental Implantology, S.L.

**Address:**

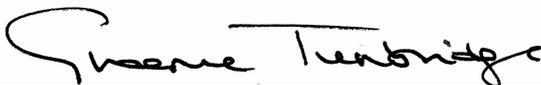
Pol. Ind. El Segre  
C/ Enginyer Mies 705-B  
Lleida  
Lerida  
25191  
Spain

**Single Registration Number:** ES-MF-000024246

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-07-01**

Current Issue Date: **2026-03-18**

Starting Validity Date: **2026-03-18**

Expiry Date: **2029-06-30**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended Purpose
Dental Implants, Abutments & Screws	The device is intended to replace missing teeth by providing stable, osseointegrated support for prosthetic restorations, such as crowns, bridges, and overdentures.

### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Dental drills and other surgical dental devices connected to active devices	Class IIa
Reusable Instruments 'Dental Instruments'	Class Ir
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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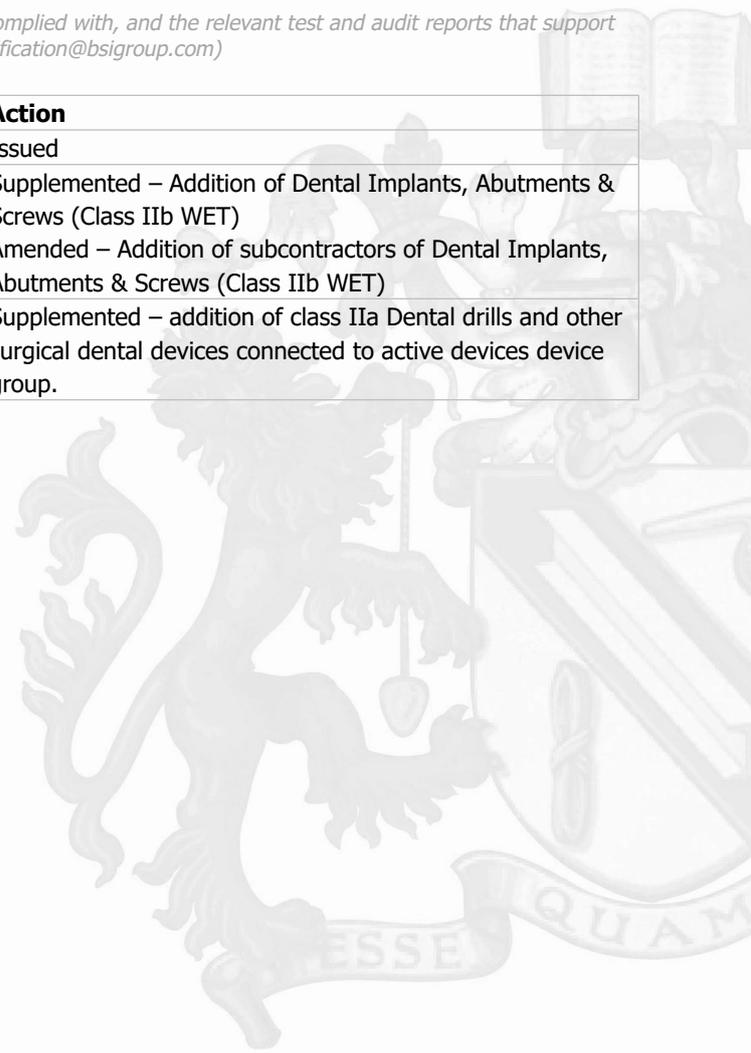
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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
2024-07-01	3787555	Issued
2025-10-15	30549063	Supplemented – Addition of Dental Implants, Abutments & Screws (Class IIb WET) Amended – Addition of subcontractors of Dental Implants, Abutments & Screws (Class IIb WET)
Current	30679145	Supplemented – addition of class IIa Dental drills and other surgical dental devices connected to active devices device group.



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