

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 650878  
**Issued To:** Ilerimplant, S.L.  
Pol. Ind. El Segre  
C/ Enginyer Mies 705-B  
Lleida  
25191  
Spain

In respect of:

**Design and manufacture of sterile dental implants, non-sterile abutments and non-sterile instruments intended for connection to an active medical device.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2016-08-05**

Date: **2019-11-14**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 650878

Issued To:

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**Spain**

| Number           | Device Name               | Intended purpose per IFU  |
|------------------|---------------------------|---|
| <b>Class IIb</b> |                           |   |
| 55849            | FRONTIER Dental Implants  | To be used to replace missing teeth in partial or total edentulous patients.  |
| 55849            | PHOENIX Dental Implants   |   |
| 55849            | AVANTGARD Dental Implants |   |
| 55849            | MONOLITH Dental Implants  |   |
| 44879            | Dental Abutments          | To be used in the prosthetic procedure in surgeries to replace missing teeth in partial or total edentulous patients.   |
| <b>Class IIa</b> |                           |   |
| MD 0401          | Dental Drills             | Dental surgical instruments connected to an active device and designed to drill the bone to a certain diameter and depth depending on the size of the implant to be placed. |

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**Spain**

**Subcontractor:**

**Service(s) supplied**

Aragogamma S.L  
Ctra. Granollers a Cardedeu, Km 3.5  
Les Franqueses del Vallés  
Barcelona  
08520  
Spain

**Radiation (Gamma Sterilization)**

FFDM TIVOLY  
78-80 Avenue de la Prospective  
Bourges Cedex  
18020  
France

**Crucial Supplier**

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## Certificate History

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 Date: **2019-11-14**  
 Issued To: **Ilerimplant, S.L.**  
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**Spain**

| Date             | Reference Number | Action   |
|------------------|------------------|--|
| 05 August 2016   | 8498317          | First Issue<br>Transfer from another Notified Body   |
| 16 October 2018  | 9651894          | Scope changed from 'Design and manufacture of sterile dental implants, abutments and non-sterile instruments for attachment to an active device.' to 'Design and manufacture of sterile dental implants, abutments, suture guides and non-sterile instruments for attachment to an active device.'<br>Addition of subcontractor Oscatech Microinyección S.L.                             |
| 07 February 2019 | 8648403          | Traceable to NB 0086.  |
| 14 November 2019 | 3095229          | Certificate renewal.<br>Reduction of scope to remove the Suture Guide Device Subcategory.<br>Clarification of scope to confirm the specific device families under certification and new product table format.<br>Crucial Supplier name update from "FFDM-PNEUMAT" to "FFDM TIVOLY".<br>Removal of Critical Subcontractor "Oscatech Microinyección S.L." for the activity of manufacture. |

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| Date  | Reference Number | Action   |
|---|------------------|--|
| <b>Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</b> |                  |  |
| 27 April 2022   | 3660524          | Legal manufacturer name change from 'Ilerimplant, S.L.' to 'GMI Dental Implantology, S.L.' |

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27 April 2022

GMI Dental Implantology, S.L.  
Pol. Ind. El Segre  
C/ Enginyer Mies 705-B  
Lleida  
25191  
Spain

To whom it may concern,

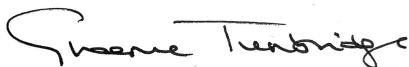
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

| <b>Certificate</b> | <b>Directive and Annex</b>             | <b>Reference Number</b> | <b>Changes approved</b>   |
|--------------------|--|-------------------------|---|
| CE 650878          | 93/42/EEC Annex II excluding Section 4 | 3660524                 | Legal manufacturer name change from 'Ilerimplant, S.L' to 'GMI Dental Implantology, S.L'. |

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
Senior Vice President, Medical Devices