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 Míes 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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Supplementary Information to CE 650878

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Number	Device Name	Intended purpose per IFU
Class IIb		
55849	FRONTIER Dental Implants	To be used to replace missing teeth in partial or total edentolous 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 edentolous patients.
Class IIa		
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.

First Issued: **2016-08-05** Date: **2019-11-14** Expiry Date: **2024-05-26**

By Royal Charter

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List of Significant Subcontractors

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

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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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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
05 August 2016	8498317	First Issue 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.' Addition of subcontractor Oscatech Microinyección S.L.
07 February 2019	8648403	Traceable to NB 0086.
14 November 2019	3095229	Certificate renewal. Reduction of scope to remove the Suture Guide Device Subcategory. Clarification of scope to confirm the specific device families under certification and new product table format. Crucial Supplier name update from "FFDM-PNEUMAT" to "FFDM TIVOLY". Removal of Critical Subcontractor "Oscatech Microinyección S.L." for the activity of manufacture.

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

Inspiring trust for a more resilient world.

27 April 2022

GMI Dental Implantology, S.L.
Pol. Ind. El Segre
C/ Enginyer Míes 705-B
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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 26th 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.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
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

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