

# EC Certificate - Full Quality Assurance System

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

**No.****CE 679150**

## Issued To:

**Inmet Garnick S.A.  
Calle Plástico 5 Nave 12  
Polígono Industrial Miralcampo  
Azuqueca de Henares  
Guadalajara  
19200  
Spain**

## In respect of:

**Design, development and manufacture of dental implant system, abutments and associated instruments**

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 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2018-02-20**Date: **2018-02-20**Expiry Date: **2023-02-19**

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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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## List of Significant Subcontractors

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

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**Spain**

| <b>Subcontractor:</b>   | <b>Service(s) supplied</b>  |
|---|-----------------------------|
| Anodime, S.L.<br>C/BESOS 19<br>Ripollet<br>Barcelona<br>08291<br>Spain  | <b>Crucial Supplier</b>     |
| FLUBETECH, S.L.<br>Pol. Ind. Can Carner. Calle Montsià 23.<br>Castellar del Vallès<br>Barcelona<br>08211<br>Spain | <b>Crucial Supplier</b>     |
| Ionisos Iberica<br>(Ionmed Esterilizacion, S.A.U.)<br>50 Rocinante St.<br>Tarancon<br>Cuenca<br>16400<br>Spain    | <b>E beam Sterilization</b> |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 679150**  
 Date: **2018-02-20**  
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| Date    | Reference Number | Action      |
|---------|------------------|-------------|
| Current | 8787003          | First Issue |

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