

EC Certificate - Full Quality Assurance System

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

No. CE 636429
Issued To: **Systhex Sistemas de Implantes Ósseo Integrado Ltda.**
Rua Procópio Ferreira Martins, 586, Cajuru
Curitiba
Paraná
82940-190
Brasil

In respect of:

Design and manufacture of sterile dental implants, abutments and accessories, cover screws and non sterile reusable dental instruments for connection to an active device.

Those aspects of Annex II related to metrological requirements in the design and manufacture of dental surgical 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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **11 August 2016**

Date: **11 August 2016**

Expiry Date: **10 August 2021**

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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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Subcontractor:**Service(s) supplied**

Bior Technologies Brasil EPP
RUA JOSÉ LUIZ FLAQUER, 13
Sorocaba
São Paulo
Brasil

Crucial Supplier

Companhia Brasileira de
Esterilizacao-CBE/Embrarad
Cruzada Bandeirante 290
Cotia
São Paulo
06705-140
Brasil

Gamma Sterilization

Obelis s.a
Boulevard Général Wahis, 53
Brussels
B-1030
Belgium

EU Representative

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Certificate History

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Date	Reference Number	Action
11 August 2016	8345518	First Issue

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