

EC Certificate - Full Quality Assurance System

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

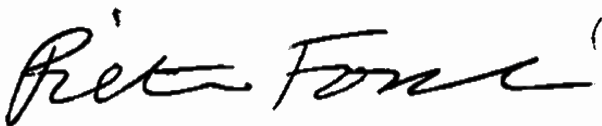
No. CE 516198
Issued To: **Implant Direct Sybron Manufacturing LLC**
3050 East Hillcrest Drive
Thousand Oaks
California
91362
USA

In respect of:

The design and manufacture of dental implants, dental abutments and related instrumentation.

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):



Pietro Foschi - Strategic Delivery Director

First Issued: **19 July 2007**

Date: **12 January 2015**

Expiry Date: **18 July 2017**

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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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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:

Certificate No: **CE 516198**
 Date: **12 January 2015**
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3050 East Hillcrest Drive
Thousand Oaks
California
91362
USA

Subcontractor:	Service(s) supplied
Cendres & Métaux SA CH-2501 Biel-Bienne Switzerland	Manufacture
DOT GmbH Charles-Darwin-Ring 1 a 18059 Rostock Germany	Manufacture
EBI Inc. #289, Wuisong-ri, Ahpryang-myeon Kyeongbuk 712-825 South Korea	Manufacture
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	EU Representative

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91362
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Subcontractor:	Service(s) supplied
Maillefer Instruments Chemin du Verger 3 Ballaigues 1338 Switzerland	Manufacture
Norsco Inc 1816 Ackley Circle Oakdale California 95361 USA	Manufacture
Orchid Unique Orthopaedic Solutions 6688 Dixie Hwy. Bridgeport Michigan 48722 USA	Manufacture

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Subcontractor:

Service(s) supplied

Rhein 83 S.r.l.
Via E Zagon
10 - 40128 Bologna
Italy

Manufacture

Sterigenics
344 Bonnie Circle
Corona
California 92880
USA

Gamma Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 516198**
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Thousand Oaks
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91362
USA

Date	Reference Number	Action
19 July 2007	-	First issue
16 June 2011	-	Change of company name from Implant Direct LLC to Implant Direct Sybron Manufacturing LLC. Clarification of certificate scope and addition of significant subcontractor Emergo Group, Molenstraat 15 2513 BH, The Hague, Netherlands for EU Representative Activity.
18 July 2012	7867506	Certificate renewal. Addition of significant subcontractors for manufacture activity: Orchid Unique Orthopaedic Solutions; Norsco Inc; EBI Inc. Removal of significant subcontractor Maillefer Instruments.
04 March 2013	7880044	Addition of DOT GmbH as a significant subcontractor following the transfer of products from Attachments International and Sybron Implant Solutions.
21 November 2013	8074224	Added Maillefer Instruments as subcontractor and corrected info for Emergo.
12 January 2015	8207630	Location of legal manufacture has changed to Thousand Oaks, California.