By Royal Charter

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 sterile 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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **19 July 2007** Date: **30 June 2015** Expiry Date: **18 July 2017**

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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:	**30 June 2015**
Issued To:	**Implant Direct Sybron Manufacturing LLC** **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 Republic of Korea	**Manufacture**
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	**EU Representative**

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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 Zago n 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**

Date: **30 June 2015**

Issued To: **Implant Direct Sybron Manufacturing LLC**
3050 East Hillcrest Drive
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.
30 June 2015	8350475	Expansion of scope to include manufacture and control of sterile product. Review and approval of clean room at Thousand Oaks facility.