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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2007-07-19** Date: **2017-07-14** Expiry Date: **2022-07-18**

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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:	**2017-07-14**
Issued To:	**Implant Direct Sybron Manufacturing LLC** **3050 East Hillcrest Drive** **Thousand Oaks** **California** **91362** **USA**

Subcontractor:	**Service(s) supplied**
Boston Centerless Inc. 11 Presidential Way Woburn Massachusetts 01801 USA	**Crucial Supplier**
Cendres & Métaux SA CH-2501 Biel-Bienne Switzerland	**Manufacture**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
HiMed 148 Sweet Hollow Rd Old Bethpage New York 11804 USA	**Other critical processes**

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By Royal Charter

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Subcontractor:	**Service(s) supplied**
Implant Direct Sybron Manufacturing LLC 8840 W. Russell Road Las Vegas Nevada 89148 USA	**Distribution** **Packaging**
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**
Perryman Company Specialty Titanium Products 18430 Brookhurst St., Ste 202G Fountain Valley California 92708 USA	**Crucial Supplier**
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

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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.

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Date	Reference Number	Action
Current	8744602	Certificate Renewal Addition of HiMed as subcontractor for HA coating (Activity type: Other Critical Processes). Addition of Implant Direct Sybron Manufacturing LLC as subcontractor (Activity: Packaging and Distribution) Addition of Perryman Company and Boston Centerless to list of subcontractors (Activity: Crucial Supplier) Update to address for EU Rep Emergo Europe. Remove DOT GmbH, EBI Inc., and Maillefer Instruments from list of subcontractors.