

# Certificate

## Full Quality Assurance

No. CE 516198



Issued to:

**Implant Direct Sybron Manufacturing**  
**27030 Malibu Hills Road**  
**Calabasas Hills**  
**California**  
**91301**  
**USA**

In respect of:

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

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.  
For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to be 'Gary Fenton', written over a horizontal line.

Gary Fenton, Global Assurance Director

First Issued: 19 Jul 2007

Date: 18 Jul 2012

Expiration Date: 18 Jul 2017

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### *Conditions of Approval*

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.  
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.

*raising standards worldwide*<sup>TM</sup>



## List of Significant Subcontractors

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

Certificate No. **CE 516198**  
Date: **18 Jul 2012**  
Issued to: **Implant Direct Sybron Manufacturing**  
**Calabasas Hills**  
**USA**

<b>Subcontractor</b>	<b>Service(s) supplied</b>
Orchid Unique Orthopaedic Solutions 6688 Dixie Hwy. Bridgeport Michigan 48722 USA	Manufacture
Norsco Inc 1816 Ackley Circle Oakdale California 95361 USA	Manufacture
EBI Inc. #289, Wuisong-ri, Ahpryang-myeon Kyeongbuk 712-825 South Korea	Manufacture
Emergo Group Molenstraat 15 2513 BH The Hague Netherlands	EU Representative

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<b>Subcontractor</b>	<b>Service(s) supplied</b>
Sterigenics 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
Cendres & Métaux SA CH-2501 Biel-Bienne Switzerland	Manufacture
Rhein 83 S.r.l. Via E Zago n 10 - 40128 Bologna Italy	Manufacture

## History of Quality Assurance Certificate

**Certificate No:** CE 516198  
**Issue Date:** 18 Jul 2012  
**Issued to:** Implant Direct Sybron Manufacturing  
Calabasas Hills  
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.