

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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'David W. Ford', written over a horizontal line.

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: 19 Jul 2007

Date: 16 Jun 2011

Expiration Date: 18 Jul 2012

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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.

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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
Emergo Group Molenstraat 15 2513 BH The Hague Netherlands	EU Representative
Sterigenics 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
Maillefer Instruments Holding SARL Chemin du Verger, 3 CH - 1338 Ballaigues Switzerland	Manufacture
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: 16 June 2011
Issued to: Implant Direct LLC
Calabasas Hills
USA

Date	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.