

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** CE 00665  
**Issued To:** **Dentsply Limited**  
**Building 3**  
**The Heights**  
**Weybridge**  
**Surrey**  
**KT13 0NY**  
**United Kingdom**

In respect of:

**The manufacture of dental mandrels, prophylaxis rotary instruments (cups and brushes), diamond, steel and tungsten carbide burs and sterile diamond burs.**

**Those aspects of Annex V relating to metrology in the manufacture periodontal measuring probes.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Gary Fenton, Global Assurance Director

First Issued: **23 May 1995**

Date: **29 August 2014**

Expiry Date: **06 September 2019**

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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 V

## List of Significant Subcontractors

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

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
GAC International, Inc. Also trading as Tiger Ortho 35.5 Knickerbocker Avenue Bohemia NY 11716 USA	<b>Manufacture</b>
M.D.T. Micro Diamond Technologies Ltd. 2 Hamal Street, P.O. Box 1063 Industrial Park Afula 18110 Israel	<b>Control of Sterilization</b> <b>Manufacture</b> <b>Packaging</b>
Maillefer Instruments Holding SARL Chemin de Beau-Site, 5 CH-1338 Ballaigues Switzerland	<b>Manufacture</b>

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**Subcontractor:**

**Service(s) supplied**

Sor-Van Radiation Ltd.  
P. O. Box 214  
Yavne  
81800  
Israel

**Gamma Sterilization**

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Date	Reference Number	Action
23 May 1995	n/a	First issue
16 February 1996	n/a	Addition of one subcontractor
11 March 1996	n/a	Change of scope
30 June 1998	n/a	Change of scope and addition of four subcontractors
7 September 2004	4729065	Removal of Good Dent Brushes, renewal and reissue of certificate in new format
09 March 2006	4815898	Change to scope to include "Sterile Diamond Burs". Addition of VDW GmbH as a subcontractor for Control of Sterilization
17 January 2008	7146549	Subcontractor "Dentsply Ash Instruments (Dentsply Ltd)" address change and addition of Gac International, Inc. Also trading as Tiger Ortho as manufacturing activity to the significant list of sub contractors.
18 December 2008	7275662	Company address change Removal of Dentsply Plymouth from the list of significant subcontractors
21 September 2009	7297177	Removal of SS White Group from the list of significant subcontractors Certificate renewal

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Date	Reference Number	Action
25 October 2010	7602521	Scope modification to differentiate periodontal measuring probes as class I measuring devices, ('Those aspects of Annex V relating to metrology in the manufacture periodontal measuring probes.)  Addition of 2 new subcontractors: 1. M.D.T. Micro Diamond Technologies Ltd., Israel, for manufacture', 'packaging' and 'Control of Sterilisation'  Sor Van Radiation Ltd., Kiryat, Israel, for 'Gamma Sterilization'
09 May 2013	7983157	Address Change from 'Building 1, Aviator Park, Station Road, Addlestone, KT15 2PG, United Kingdom' to 'Building 3, The Heights, Weybridge, Surrey, KT13 0NY, United Kingdom'
29 August 2014	8210395	Certificate Renewal and removal of "VDW GmbH" as Subcontractor