

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 668748
Issued To: **Dentsply LLC**
also dba Dentsply Caulk
38 West Clarke Avenue
Milford
Delaware
19963
USA

In respect of:

Design, development and manufacture of dental cements, adhesives/bonding agents, dental composites, amalgam alloys, bases, liners, crown and bridge materials, orthodontic resins, finishing and polishing materials, conditioners/etchants, matrix systems, restorative instruments and desensitizers.

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-11-28**

Date: **2019-11-29**

Expiry Date: **2024-05-26**

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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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Dentsply DeTrey GmbH De-Trey Str. 1 78467 Konstanz Germany	EU Representative
Maillefer Instruments Holding Sàrl Chemin du Verger 3 1338 Ballaigues Switzerland	Manufacture
Pulpdent Corporation 80 Oakland Street Watertown Massachusetts 02471-0780 USA	Manufacture

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Certificate History

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Date	Reference Number	Action
28 November 2017	8688908	First Issue.
27 February 2019	8963069	Traceable to NB 0086.
Current	3096495	Certificate Renewal. Update of Subcontractor name from Dentsply Maillefer to Maillefer Instrumnets Holding Sàrl.

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