

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, 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: **2021-04-21**

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:

Certificate No: **CE 668748**
Date: **2021-04-21**
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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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 668748**
 Date: **2021-04-21**
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38 West Clarke Avenue
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Date	Reference Number	Action
28 November 2017	8688908	First Issue.
27 February 2019	8963069	Traceable to NB 0086.
29 November 2019	3096495	Certificate Renewal. Update of Subcontractor name from Dentsply Maillefer to Maillefer Instrumnets Holding Sàrl.
Current	3412516	Reduction of scope by removing "Amalgam alloys".

Dentsply LLC dba Dentsply Caulk
38 W. Clarke Avenue
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2023-09-27

Notified Body Confirmation Letter
Reference: EU2023-607/667569

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Dentsply LLC dba Dentsply Caulk
38 W. Clarke Avenue
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19963
USA

US-MF-000016555

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

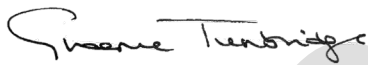
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,



Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Enhance	Class IIa	N/A	CE 668748, NB# 2797
PoGo	Class IIa	N/A	CE 668748, NB# 2797
Dycal	Class IIa	N/A	CE 668748, NB# 2797
EsthetX HD	Class IIa	N/A	CE 668748, NB# 2797
SureFil	Class IIa	N/A	CE 668748, NB# 2797
EsthetX flow	Class IIa	N/A	CE 668748, NB# 2797
SDR Plus	Class IIa	N/A	CE 668748, NB# 2797
core-X flow	Class IIa	N/A	CE 668748, NB# 2797
Calibra	Class IIa	N/A	CE 668748, NB# 2797
SmartCem2	Class IIa	N/A	CE 668748, NB# 2797
Fynal	Class IIa	N/A	CE 668748, NB# 2797
IRM	Class IIa	N/A	CE 668748, NB# 2797
ZOE B&T	Class IIa	N/A	CE 668748, NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Aquasil	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives
Ultra	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives
Ultra+	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives
Reprosil	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Quixx	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives
Regisil 2X	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives
PB	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives
Rigid	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	Action
2023/09/27	Initial issue