

EC Certificate - Production Quality Assurance

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

No. CE 623238
Issued To: Dentonics, Inc.
2833 Tophill Road
Monroe
North Carolina
28110
USA

In respect of:

The manufacture of dental cements, liners, etchants, sealants, restorative materials, orthodontic adhesives, root canal filling materials, temporary crown and bridge materials.

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-01-27**

Date: **2020-11-05**

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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Supplementary Information to CE 623238

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28110
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Class	IIa
Number	Device Name
SMD 0402	Cements and Liners
SMD 0402	Restoratives
SMD 0402	Specialties
SMD 0402	Preventives
SMD 0402	Provisionals



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This certificate was issued electronically and is bound by the conditions of the contract.

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