

EC Certificate - Production Quality Assurance

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

No. CE 710688
Issued To: **Kerr Corporation,
Also Doing Business as
Pentron Clinical
200 S. Kraemer Blvd.
Brea
California
92821
USA**

In respect of:

The manufacture of endodontic materials, dental composite materials and accessories, dental cements, dental sealants, fiber posts and associated sterile and non-sterile dental and endodontic instruments for attachments to an active device.

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: **2019-05-16**

Date: **2019-08-27**

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
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	Gamma Irradiation
Kerr Italia S.r.l. Via Passanti, 332 Scafati (SA) 84018 Italy	EU Representative Manufacture
Life Science Outsourcing, Inc. 830 Challenger Street Brea California 92821 USA	Control of Sterilization Packaging

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Subcontractor:

Service(s) supplied

Ormex S. de R.L. de C.V.
 A Subsidiary of Ormco Corporation
 Calle 21 No. 1103 AMP CD Industrial
 Uman
 Yucatan
 97390
 Mexico

Manufacture

SDS de Mexico S. de R.L. de C.V.,
 A Subsidiary of Ormco Corporation
 Circuito Sur No. 31
 Parque Industrial Nelson
 Mexicali
 Baja California
 C.P.21395
 Mexico

Packaging

SpofaDental a.s
 Markova 238
 Jicín
 CZ-506 01
 Czech Republic

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
16 May 2019	9767307	First Issue. Mirror certificate of CE 00847
Current	3054471	Certificate Renewal.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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