

EC Certificate - Production Quality Assurance

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

No.**CE 00847****Issued To:**

**Kerr Corporation,
Also Doing Business as
Pentron Clinical
1717 West Collins Avenue
Orange
California 92867
USA**

In respect of:

The manufacture of endodontic materials, dental composite materials and accessories, dental adhesives, cements, dental sealants, fiber posts, and associated sterile and non-sterile dental and endodontic instruments, finishing and polishing instruments for attachment 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: 1995-08-29**Date: 2021-04-30****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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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:

Certificate No: **CE 00847**
 Date: **2021-04-30**
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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, 174 Scafati Salerno 84018 Italy	EU Representative Labelling Manufacture Packaging
KerrHawe S.A. Via Strecce 4 Bioggio 6934 Switzerland	Manufacture

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Subcontractor:	Service(s) supplied
Life Science Outsourcing, Inc. 830 Challenger Street Brea California 92821 USA	Control of Sterilization Packaging
Meta Biomed Vina One Member Limited Liability Company Lot N-1 B, No.4 Road Extended Long Hau Industrial Park, Hamlet 3 Long Hau Commune Can Giuoc District Long An Province Vietnam	Labelling Manufacture 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	Labelling Manufacture Packaging
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	Labelling Manufacture Packaging
SpofaDental a.s Markova 238 506 01 Jicin Czech Republic	EU Representative Labelling Manufacture Packaging

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Date	Reference Number	Action
29 August 1995	-	First issued.
05 November 1997	-	Address change.
19 November 2004	-	Revised wording of scope from 'dental composite restorative materials' to 'dental composite restorative systems'. Certificate renewal and reissue in new format.
05 July 2006	-	Correction to company name from Kerr Dental Materials Centre to Kerr Corporation.
07 September 2009	7437306	Addition of 'Kerr Italia, SpA' as EU Representative Certificate renewal.
05 November 2009	7452138	Company name changed, addition of "Also Doing Business as Pentron Clinical" Addition of 3 new subcontractors, "Pentron Clinical Technologies, LLC" for manufacturing, "SDS de Mexico SA de C.V" for packaging, and CPartner4U for EU Rep. subcontractor activities Changed the subcontractor name for the Kerr EU rep from Kerr Italia Spa to Kerr Italia S.r.l.
26 October 2010	7596167	Clarification of scope and removal of the subcontractor Pentron Clinical Technologies, LLC, 68 North Plains Industrial Road, Wallingford, CT 06492, USA.
27 August 2014	8166389	Certificate Renewal, removal of CPartner4U and addition of "SpofaDental" as EU representative for Pentron product lines.

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

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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Date	Reference Number	Action
17 December 2015	8432946	Addition of Dux Dental, Oxnard, California and Kerr Italia S.r.l, Salerno, Italy for the activity manufacture.
01 November 2017	8787277	<p>Addition of Significant Subcontractors:</p> <ul style="list-style-type: none"> Plexus (Xiamen) Co., Ltd., No.6 Xiangxing 2 Road, Modern Logistics Zone (Free Trade Zone) Xiamen City, Fujian Province, 361006, China for Manufacture, Packaging and Control Sterilization activities. Anhui Tiankang Medical Technology Co., Ltd. No. 228 Weiyi Road Economic Development Zone Tianchang City, 239300 Anhui China for Sterilization activity <p>Expansion of scope to include "EndoVac Pure with sterile tip attachments".</p>
26 June 2018	8926842	<p>Addition of Significant Subcontractors related to the manufacturing and sterilization of Class IIa Endodontic Files:</p> <ul style="list-style-type: none"> Ormex S. de R. L. de C. V., Uman Yucatan 97390 Mexico for Manufacture Life Science Outsourcing, Inc., 830 Challenger Street, Brea, CA 92821, USA for Packaging & Control of Sterilization Isomedix Operations, Inc., 1000 S. Sarah Place, Ontario, California, 91761, USA for Gamma Irradiation <p>Alignment of scope of certificate to appropriately represent products covered.</p>

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Date	Reference Number	Action
15 January 2019	7946170	Traceable to NB 0086.
16 May 2019	9767307	Removal of Endovac Pure system from the scope. Removal of three subcontractors: Dux Dental, Anhui Tiankang Medical and Plexus (Xiamen) Co. Ltd.
27 August 2019	3054471	Certificate Renewal.
05 October 2020	3252057	Clarification of scope to include "adhesives" Addition of Subcontractor, Meta Biomed Vina One Member Limited Liability Company Lot N-1 B, No. 4 Road Extended Long Hau Industrial Park, Hamlet 3, Long Hau Commune, Can Giuoc District, Long An Province, Vietnam Clarification of services supplied by subcontractors, Kerr Italia, Ormex and SDS de Mexico.
17 March 2021	3387291	Expand scope to include "and polishing instruments for attachment to an active device" Addition of Subcontractor, KerrHawe S.A. Via Strecce 4 Bioggio 6934 Switzerland Change address of EU Rep Kerr Italia S.r.l. to, Kerr Italia S.r.l Via Passanti, 174 Scafati (SA) 84018, Italy.

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Date	Reference Number	Action
Current	3421300	Expand scope to add "finishing" Added "Manufacture", "Labelling", "Packaging" to services supplied for subcontractor: SpofaDental a.s. Markova 238 506 01 Jicin Czech Republic

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