By Royal Charter

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**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

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

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** **Labelling** **Manufacture** **Packaging**
Life Science Outsourcing, Inc. 830 Challenger Street Brea California 92821 USA	**Control of Sterilization** **Packaging**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

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

Subcontractor:	**Service(s) supplied**
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**
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**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

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

Subcontractor:	**Service(s) supplied**
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**

...making excellence a habit.™

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

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

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 CEpartner4U 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 CEPartner4U and addition of "SpofaDental" as EU representative for Pentron product lines.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

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

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	Addition of Significant Subcontractors: • 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 Expansion of scope to include "EndoVac Pure with sterile tip attachments".
26 June 2018	8926842	Addition of Significant Subcontractors related to the manufacturing and sterilization of Class IIa Endodontic Files: • 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 Alignment of scope of certificate to appropriately represent products covered.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

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

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.

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

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

Date	Reference Number	Action
30 April 2021	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
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
17 June 2021	3333588	Addition of eIFU to meet the requirements of Regulation EU/207/2012.

Inspiring trust for a more resilient world.

June 17, 2021

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 00847	93/42/EEC Annex V, Section 3.2 (2007/47)	3333588	Addition of eIFU to meet the requirements of Regulation EU/207/2012.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl