

# EC Certification

# Intertek

**FULL QUALITY ASSURANCE SYSTEM**  
**Directive 93/42/EEC for Medical Devices, Annex II (OBL)**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II of the Directive 93/42/EEC on medical devices via an Own Branding arrangement. We certify that the full quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

## RELIANCE ORTHODONTICS PRODUCTS, INC

1540 West Thorndale Avenue, Itasca, IL 60143, USA

Orthodontic Wires  
Dental rotary instrument burs

**Certificate Number:** 227 A CE  
**Initial Certification Date:** 20 November 2013  
**Certificate Effective Date:** 20 November 2013  
**Certificate Expiry Date:** 19 November 2018



*Brian Johnson*  
AMTAC Certification Services Limited, Milton Keynes, UK  
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

*Kopija Talwa,*  
*P. Paschimurmas*

Intertek Intertek Intertek Intertek Intertek

# EC Certificate - Production Quality Assurance

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

**No.** CE 00849  
**Issued To:** **Ormco Corporation**  
**also trading as Sybron Endo**  
**1332 South Lone Hill Avenue**  
**Glendora**  
**California**  
**91740**  
**USA**

In respect of:

**The manufacture of orthodontic appliance systems, active devices and accessories for orthodontic and restorative dentistry, and devices for endodontic diagnosis and treatment.**

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 0086):



Gary Fenton, Global Assurance Director



Kapija Telera  
P. Zastierciwlas

First Issued: **29 August 1995**

Date: **28 August 2014**

Expiry Date: **28 August 2019**

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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.

# 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 00849**  
 Date: **28 August 2014**  
 Issued To: **Ormco Corporation**  
**also trading as Sybron Endo**  
**1332 South Lone Hill Avenue**  
**Glendora**  
**California**  
**91740**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Kerr Corporation 1717 West Collins Avenue Orange California 92867 USA	<b>Manufacture</b>
Kerr Corporation 28200 Wick Road Romulus Michigan 48174-2600 USA	<b>Manufacture</b>
Kerr Italia S.r.l. Via Passanti, 332 Scafati (SA) 84018 Italy	<b>EU Representative</b>

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# EC Certificate - Production Quality Assurance

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

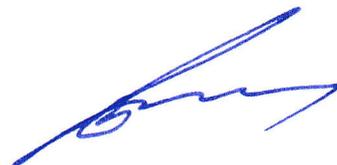
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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Meta Biomed (Cambodia) Co.,Ltd Path, Village Trapeng Tleng, Sangat, Chaum Chao Khan Dangkor, Phnom Penh, 00000 Cambodia	<b>Manufacture</b>
Meta Biomed, Co., Ltd 634 Yeonje-Ri Gang-Oe-Myeon Cheong-Won-Gun Chungcheongbuk-Do 363-951 South Korea	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Metrex Research LLC dba Surgical Acuity, Orasoptic and Kerr Corporation 3225 Deming Way Suite 190 Middleton Wisconsin 53562 USA	<b>Manufacture</b>
Ormex S. de R.L. de C.V. A Subsidiary of Ormco Corporation Calle 21 No. 1103 AMP CD Industrial Uman Yucatan 97390 Mexico	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
SDS de México S. de R.L. de C.V. Circuito Sur No. 31 C.P. 21395 Mexicali, B.C. Mexico	<b>Manufacture</b>

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# EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
29 August 1995	-	First issue
17 December 1996	-	Addition of accessories tools and moulded and extruded elastomeric products
07 August 1998	-	Deletion of products including wires, bands, brackets and accessory tools, moulded and extruded elastomeric products and adhesives and replacement with appliance systems and devices for endodontic diagnosis and treatment
19 November 2004	-	Analytic corporate name change to Sybron Endo, Certificate renewal and reissue in new format
08 September 2009	7437307	Change of name/address to include 'also trading as Sybron Endo'. Addition of subcontractors; 'Kerr Corporation, WI 53562' for manufacture, 'Endodont Inc, CA 91010' for manufacture and 'Kerr Italia SpA' for EU representative. Removal of subcontractor; 'Sybron Endo'. Certificate renewal
08 July 2010	7546612	Minor address change, from '1332 South <b>Loan</b> Hill Avenue' to '1332 South <b>Lone</b> Hill Avenue'

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK4 9DD Tel: +44 (0)145 909 0000



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Date	Reference Number	Action
21 February 2011	7649110	Amendments made to the sub contractors names: From 'Ormex SA de CV, 21 No. 1103 AMP CD Industrial' to 'Ormex S. de R.L. de C.V. , Calle 21 No. 1103 AMP CD Industrial'. From 'SDS de Mexico' to 'SDS de Mexico S. de R.L. de C.V.'.
24 October 2013	7916782	Expansion of scope to include active orthodontic devices and accessories. Update to list of subcontractors. Removed Endodent Inc. Added META BIOMED (CAMBODIA) CO.,LTD and META BIOMED, CO., LTD (Korea) for manufacture activities.
15 April 2014	8138477	Addition of Kerr Orange and Kerr Romulus as Subcontractors. Clarification of scope: Changed "active orthodontic devices and accessories" to "active devices and accessories for orthodontic and restorative dentistry"
01 July 2014	8176875	Correction of postal code for subcontractor SDS de Mexico.
28 August 2014	8196431	Certificate renewal

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