Declaration of Conformity

PRODUCT IDENTIFICATION	
PRODUCT Name	Project Number
SEALAPEX / SEALAPEX XPRESS	SE1114

MANUFACTURER	
Name of Company	Address
☐ ORMCO ☐ SYBRON IMPLANT SOLUTIONS ☐ SYBRON ENDO ☐ OTHER	1332 S. Lone Hill Avenue Glendora, CA 91740 United States

AUTHORIZED REPRESENTATIVE	
Name of Company	Address
Kerr Italia S.r.l.	Via Passanti, 3332 I-84018 Scafati (SA), Italy

NOTIFIED BODY (If Applicable)	NOTIFIED BODY NUMBER (If Applicable)	
Notified Body Name BSI	Notified Body Number 0086	☐ Sterile ☐ Measuring Function
CE Certificate Number 00849	*FIELD TO BE COMPLETED BY QA MANAGEMENT ONLY*	

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class IIa	Annex V and VII of MDD 93/42/EEC Council Directive	ISO 13485:2003 ISO 14971:2007

Declaration for systems and procedure packs:

☐ Ormco Corporation declares that mutual compatibility of the devices within the system have been verified in accordance with the instructions, has packaged the system or pack and supplied relevant information to users and whole activity is subjected to appropriate methods of internal control and inspection.

Ormco Corporation declares that the above mentioned products meet the provision of the Council of Directives 93/42/EEC for Medical Devices. Ormco Corporation is the natural and legal organization with responsibility for the design, manufacture, packaging, and labeling before the device is placed on the mark under his own name, regardless whether these operations are carried out by this manufacturer or on his behalf by a party.

Product Development — Date 10/20/09

Gary Garman

Quality Assurance — Date 10/29/09

Greg Amano

Form – 1048
Revision 8/20/09
Reference SOP 4-111

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