



Declaration of Conformity

PRODUCT IDENTIFICATION	
PRODUCT Name	Project Number
Endopore, Entegra, SybronHEX Plus Implant Lines (see revision 8/6/10 component list in section 3)	SIS TF 308

MANUFACTURER	
Name of Company	Address
SYBRON IMPLANT SOLUTIONS	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 <u>BSI</u>	Notified Body Number <u>0086</u>	<input checked="" type="checkbox"/> Sterile <input type="checkbox"/> Measuring Function
CE Certificate Number <u>CE 516142</u> FIELD TO BE COMPLETED BY QA MANAGEMENT ONLY		

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class <u>IIB</u>	Annex <u>II</u> of MDD 93/42/EEC Council Directive	ISO 13485:2003 ISO 14971:2007
Declaration for systems and procedure packs: <input type="checkbox"/> Sybron Implant Solutions 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.		

Sybron Implant Solutions declares that the above mentioned products meet the provision of the Council of Directives 93/42/EEC for Medical Devices. Sybron Implant Solutions 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.

8/9/10

 Product Development Date

8-10-10

 Quality Assurance Date

Name: Irene Poespowidjojo

Name: Mark Dzendzel