



EC DECLARATION OF CONFORMITY

DEC-960920-revC

This declaration of conformity is issued under the sole responsibility of the manufacturer

• Manufacturer's Name:	Metrex Research, LLC dba Orasoptic
• Manufacturer's Address:	3225 Deming Way, Suite 190 Middleton, WI 53562 USA
• Authorized Representative within the Community:	Kerr Italia, Srl Via Passanti, 332 I-84018 Scafati (SA), Italy
• Device Classification:	Class I
• Model:	Orasoptic Loupes
• Product Number(s):	Defined by Oracle Configurator, see CE technical file for details.
• Device Identification:	000000-999999
• Application of Council Directive(s):	93/42/EEC as amended by 2007/47/EC 2011/65/EU
• Standard(s) to which Conformity is Declared:	EN 50581:2012 EN 62321:2009 ISO 13485 ISO 14971
The object of the declaration described above is in conformity with Directive 93/42/EEC concerning medical devices as amended by 2007/47/EC, and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.	
Date of Issue:	February 28, 2014
Place of Issue:	Metrex Research, LLC dba Orasoptic, Middleton, WI USA
 James Onderak, Director of I2E	 James Chenard, Director of Quality