

EC DECLARATION OF CONFORMITY

DEC-960920-revC

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

<ul style="list-style-type: none"> • Manufacturer's Name: 	<p>Metrex Research, LLC dba Orascoptic</p>
<ul style="list-style-type: none"> • Manufacturer's Address: 	<p>3225 Deming Way, Suite 190 Middleton, WI 53562 USA</p>
<ul style="list-style-type: none"> • Authorized Representative within the Community: 	<p>Kerr Italia, Srl Via Passanti, 332 I-84018 Scafati (SA), Italy</p>
<ul style="list-style-type: none"> • Device Classification: 	<p>Class I</p>
<ul style="list-style-type: none"> • Model: 	<p>Orascoptic Loupes</p>
<ul style="list-style-type: none"> • Product Number(s): 	<p>Defined by Oracle Configurator, see CE technical file for details.</p>
<ul style="list-style-type: none"> • Device Identification: 	<p>000000-999999</p>
<ul style="list-style-type: none"> • Application of Council Directive(s): 	<p>93/42/EEC as amended by 2007/47/EC 2011/65/EU</p>
<ul style="list-style-type: none"> • Standard(s) to which Conformity is Declared: 	<p>EN 50581:2012 EN 62321:2009 ISO 13485 ISO 14971</p>
<p>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.</p>	
Date of Issue:	February 28, 2014
Place of Issue:	Metrex Research, LLC dba Orascoptic, Middleton, WI USA
 James Onderak, Director of I2E	 James Chenard, Director of Quality

