




# EC Declaration of Conformity (Directive 93/42/EEC)

<i>We,</i>	
<b>Manufacturer's Name:</b>	Mortara Instrument, Inc.
<b>Manufacturer's Address:</b>	7865 North 86th Street Milwaukee, WI 53224 USA
<i>declare under our sole responsibility, that to the best of our knowledge, the product(s):</i>	
<b>Product Name:</b>	X-Scribe Stress Testing System
<b>Part Number:</b>	XSCRIBE-XXX-XXXXX (X designates alpha characters denoting specific version and system configuration management codes important for post-distribution servicing.)
<b>Lot and/or Serial Number(s):</b>	101090004151 and subsequent
<b>Product Options (Configurations):</b>	Direct or Wireless options, With / without R-Scribe software, TTL Output, Laser Printer or Thermal Printer, Treadmill or Ergometer; Remote Workstation, Tango (™) with / without SpO2, Remote Keypad.
<b>GMDN Code and Term:</b>	[36145] STRESS EXERCISE MONITORING SYSTEM, CARDIAC
<b>Class (according to the criteria of Annex IX, 93/42/EEC):</b>	Ila (Rule 10)
<i>are in conformity with the dispositions of the directive which are applicable to them. This declaration is based on the following elements:</i>	
	<ul style="list-style-type: none"><li>• Technical file (ref. X-Scribe, ANNEX VI) to demonstrate the conformity of the product to the essential requirements (ANNEX I).</li><li>• The EC Certificate ANNEX II N° 0178/B2P3/1 for approval of full quality assurance system.</li></ul>
<b>Notified Body:</b>	LNE/G-MED (N0 0459) 1 rue Gaston Boissier 75724 Paris Cedex 15 France
<b>European Union Representative:</b>	Mortara Rangoni Europe, Srl (European Headquarters, Italy) Via Cimara 103-105 40033 Casalecchio di Reno, BO
<b>Identification of Individual Signing/Location:</b>	
	Laura M. Spiegelhoff Mortara Instrument, Inc. 7865 North 86th Street Milwaukee, WI 53224 USA
<b>Date:</b>	29-April-08