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

We,

Manufacturer's Name:	Mortara Instrument, Inc.
Manufacturer's Address:	7865 North 86th Street Milwaukee, WI 53224 USA

declare under our sole responsibility, that to the best of our knowledge, the product(s):

Product Name(s):	RScribe Electrocardiograph
Part Number(s):	RSCRIBE-5XX-XXXXX (X designates alpha characters denoting system configuration management codes important for post distribution servicing)
Product Options (Configurations):	Language, printer, monitor, software
Lot and/or Serial Number(s):	SN – "1YYWWXXXXXXX" (Where YY = 2 digit year; WW = week code; and XXXXXXX = unique number starting at 0000001)
GMDN Code and Term:	[11407] – Electrocardiograph, General Purpose
Class (according to the criteria of Annex IX, 93/42/EEC):	IIa (Rule 10)

are in conformity with the dispositions of the directive which are applicable to them.
This declaration is based on the following elements:

Directive 93/42/EEC:	The ISO 13485 Certificate N° 7473 for approval of the quality system. The EC Certificate ANNEX II N° 7472 for approval of the quality system. Technical file (ref. RScribe 5, ANNEX VII) to demonstrate the conformity of the product to the essential requirements (ANNEX I).
Notified Body:	LNE/G-MED (N° 0459) 1 rue Gaston Boissier 75724 Paris Cedex 15 France
European Union Representative:	Mortara Rangoni Europe, Srl (European Headquarters, Italy) Via Cimarosa 103-105 40033 Casalecchio di Reno, BO
Identification of Individual Signing/Location:	Charles Morreale Director of Regulatory Affairs and Quality Assurance Mortara Instrument, Inc. 7865 North 86TH Street Milwaukee, WI 53224 USA
Date:	June 13, 2012