



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: X-Scribe Stress Exercise Testing System
Part Number: XSCRIBE-XXX-XXXXX, XSCRIBE-5XX-XXXXX
(X designates alpha characters denoting system configuration management codes important for post distribution servicing)
Product Options (Configurations): Direct or wireless options, with/without R-Scribe software, TTL Output, Laser or Thermal Printer, Treadmill or Ergometer, Remote Workstation, Tango™ with/without SpO2, Remote Keypad
Lot and/or Serial Number(s): SN – "1YYWWXXXXXXXX"
(Where YY = 2 digit year;
WW = week code; and
XXXXXXXX = unique number starting at 0000001)
GMDN Code and Term: [36145] – Stress Exercise Monitoring System, Cardiac
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. X-Scribe, ANNEX VII) to demonstrate the conformity of the product to the essential requirements (ANNEX I).

Notified Body: LNE/G-MED (N° 0459)
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France

European Union Representative: Mortara Rangoni Europe, Srl
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Identification of Individual Signing/Location:
Charles Morreale
Director of Regulatory Affairs and Quality Assurance
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Date: December 14, 2012