



EC Declaration of Conformity

(Directive 93/42/EEC)
(Directive 1999/5/EC)

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: T12x Ambulatory Transmitter

Part and/or Serial Number(s): T12-XXX-XXXXX
T12S-XXX-XXXXX

("X" is last 8 characters designates alpha characters denoting system configuration management codes important for post-distribution servicing)

Product Options (Configurations): T12X 2500 (2400 – 2483.5 MHz)

GMDN Code and Term: [36367] TELEMETRY SYSTEM TRANSMITTER – ELECTROCARDIOGRAPHS

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: EC Certificate, No.: 0178/B2P3/1 Annex II Point 3 Directive 93/42/EEC approval of full quality assurance system.

Technical file (ref. T12x Transmitter, ANNEX VII) to demonstrate the conformity of the product to the essential requirements (ANNEX I).

Directive 1999/5/EC: Technical File (ref. T12x Transmitter, Annex IV) to demonstrate the conformity of the product, including all applicable options, to the essential requirements (Article 3).

Notified Body: LNE/G-MED (No. 0459)
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European Union Representative: Mortara Rangoni Europe, Srl
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Identification of Individual Signing/Location: 
Laura M. Spiegelhoff

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