



EC Declaration of Conformity

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

Manufacturer's Name:

We,
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
USA

Manufacturer's Address:

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

Product Name:

X12+ Ambulatory Transmitter
X12PLUS-XXX-XXXX
("X" in last 8 characters designates alpha characters
denoting system configuration management codes important
for post-distribution servicing)

Part Number:

Lot and/or Serial Number(s):

109070014461 and subsequent

Product Options (Configurations):

X12PLUS 2500 (2400.0 – 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:

- Technical file (ref. ref. X12+, ANNEX VII) to demonstrate the conformity of the product to the essential requirements (ANNEX I).
- The EC Certificate ANNEX II N° 0178/B2P3/1 for approval of full quality assurance system.

Directive 1999/5/EC on radio equipment and telecommunications terminal equipment:

- Technical file (ref. X12+, Annex IV) to demonstrate the conformity of the product, including all applicable options, to the essential requirements (Article 3).

Notified Body:

LNE/G-MED (N0 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:

Laura M. Spiegelhoff
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
USA

Date:

08-May-2009