EC Declaration of Conformity
(Directive 93/42/EEC), (Directive 1999/5/EEC) (Directive 2011/65/EU)

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:	X12+ Ambulatory Transmitter
Part Number:	X12PLUS-XXX-XXXXX (X designates alpha characters denoting system configuration management codes important for post distribution servicing)
Product Options (Configurations):	X12PLUS 2500 (2400.0 – 2483.5 MHz)
Lot and/or Serial Number(s):	109070014461 and subsequent SN – "1YYWWXXXXXX" (Where YY = 2 digit year; WW = week code; and XXXXXXX = unique number starting at 0000001)
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:	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. X12+, ANNEX VII) to demonstrate the conformity of the product to the essential requirements (ANNEX I).
Directive 1999/5/EC	Technical file (ref. X12+ 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 (N° 0459) 1 rue Gaston Boissier 75724 Paris Cedex 15 France
European Union Representative:	Mortara Instrument Europe, Srl (European Headquarters, Italy) Via Cimarosa 103-105 40033 Casalecchio di Reno, BO
Identification of Individual Signing/Location:	 Mark Elliott VP, Global QA/RA Mortara Instrument, Inc. 7865 North 86TH Street Milwaukee, WI 53224 USA
Date:	April 14, 2017