



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:*

Product Name: H3+
Catalogue Number: H3PLUS-XXX-XXXXX
(X designates alpha characters denoting system configuration management codes important for post-distribution servicing)
Serial Number(s): 105100001165 and subsequent
Product Options (Configurations): Domestic, International
Class: IIa

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

- technical file (ref.H3+, ANNEX VII) to demonstrate the conformity of the product, including all applicable options, to the essential requirements (ANNEX I),
- the EC Certificate ANNEX II N°0178/B2P3/1 for approval of the quality system,
- the ISO 13485 Certificate N° 0178/13485/3 for approval of the quality system.

Notified Body: LNE/G-MED (N° 0459)
1, Rue Gaston Boissier 75724
Paris, France

Identification of Individual Signing/Location: Mortara Instrument, Inc.
Manager of Quality Assurance and Regulatory Affairs

Harlan L. Van Matre
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
USA

Date: 01-April-05