



# 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:** Z 200+ Thermal Writer  
**Catalogue Number** 34000-02X-1000  
**Serial Number(s):** 104294169163 and subsequent  
**Product Options (Configurations):** NA  
**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. Z 200+, 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:** G-MED (N° 0459)  
33 Avenue du Général Leclerc, BP8,  
92260 Fontenay-aux-Roses - 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:** 16-July-04