



# 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:** Adhesive Pouch  
**Part Numbers:** Surveyor S4: 8485-030-50  
H3+: 8485-031-50  
**Product Options (Configurations):** Not Applicable  
**Lot and/or Serial Number(s):** Not Applicable  
**GMDN Code and Term:** [45517] – Telemetry Bag  
**Class (according to the criteria of Annex IX, 93/42/EEC):** I (Rule 1)

*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.  
Technical file (ref. Carry Case, ANNEX VII) to demonstrate the conformity of the product to the essential requirements (ANNEX I).

**Notified Body:** Self Declaration

**European Union Representative:** Mortara Instrument Europe, Srl  
(European Headquarters, Italy)  
Via Cimarosa 103-105  
40033 Casalecchio di Reno, BO

**Identification of Individual Signing/Location:**  
  
Tim Field  
Senior Vice President, Quality

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

**Date:** February 12, 2015