

# DECLARATION OF CONFORMITY

We (Supplier's name) SPIRIT MEDICAL CO., LTD.

(Address) 3<sup>RD</sup> FL., NO. 12, LANE 1, YUNG-AN S. RD., SEC. 1, LUCHOU  
TAIPEI HSIEN, TAIWAN, R.O.C.

The sanitary products ( **LCD Display Sphygmomanometer** )  
**CK-E301 Series 、 CK-E401 Series 、 CK-801 、 CK-E420**

**The conformity assessment complies with the Annex V of 93/42/EEC as amended  
by 2007/47/EC of the following harmonized standards:**

**EN 980: 2008                      EN 1041: 2008                      EN ISO 14971: 2007**  
**EN ISO 10993-1: 2009    EN 1060-1:1995 +A1:2002    EN 1060-3:1997+A1:2005**  
**EN 1060-4: 2004                      EN 60601-1-2: 2007**  
**EN 60601-1-1: 1990 + A1: 1993 +A2:1995**

which applies to them, and therefore assures the absence any endangering of the health and safety of persons, provided the that product is used for its envisaged purpose, as well as offering the qualities assigned to it.

UNDERTAKES to establish and to keep up to date a systematic procedure to review the experience acquired with the products in the phase after production, using the opportune means to apply the necessary corrective measures, and also UNDERTAKES to inform the competent authorities as to the following situations as soon as they become known:

- a) Any defective functioning or alteration of the characteristics of its features, as well as any inadequacy of the labeling or instructions for the use of the product which could give rise to or may have caused death or severe alteration of the state of health of a patient or of a user.
- b) Any technical or sanitary reason, related with the characteristics or the features of a product, for the reasons indicated in the previous paragraph which may have led the manufacturer to systematically withdraw products of the same type from the market.

**EU Authorized Representative : SPIRIT MEDICAL UK**  
**Address: 68 Hardy St, Maidstone, Kent, ME14 2SJ, UK**

(Place and date of Issue)

TAIPEI, TAIWAN  
MAY 26, 2010

( Name and signature of authorized person)



STEVEN YAN