DECLARATION OF CONFORMITY

MANUFACTURER:	FORTUNE MEDICAL INSTRUMENT CO 6FL., NO. 29, SEC. 2, JHONGJHENG E. RD., DANSHUEI DIST, NEW TAIPEI CITY 251, TAIWAN
FACILITY:	FORTUNE MEDICAL INSTRUMENT CORP. NO. 256, CHANGCHUN 2ND RD., JHONGLI CITY, TAOYUAN COUNTY 320, TAIWAN
EUROPEAN REPRESENTATIVE:	PRIM, S.A. C/F 15, POL. IND. NO. 1, 28938 MOSTOLES. MADRID, SPAIN TEL: 34 91 334 4334 FAX: 34 91 334 2490
PRODUCT:	Resuscitator and accessories
NO. OF PRODUCT:	1610, 1690,1601,1602,1603,1604,1605,1606, 1607, 1609 series
CLASSIFICATION:	Class IIa, Rule 2 (According to annex IX of the MDD)
GMDN CODE NO. :	17591, 36086
CONFORMITY ASSESSMENT ROUTE:	Annex II.3

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	MDD 93/42/EEC , INCLUDING 2007/47/EC, EN ISO 9001/ EN ISO 13485, EN ISO 10993, EN 980
NOTIFIED BODY:	British Standard Institution Kitemark Court, Da y Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.
(EC) CERTIFICATE:	CE 588902
START OF CE MARKING:	Dec. 7, 1998

MANAGEMENT REPRESENTATIVE: Lien Ping Wang

SIGNATURE:

PLACE, DATE OF ISSUE: Taiwan, Jun 23, 2014