DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	Shenzhen ECGMAC Medical Electronics Co.,Ltd. 2nd floor of Block 2 Haoye Industrial Park, Tiegang Road ,Xixiang street,Baoan District,518102 Shenzhen,PEOPLE'S REPUBLIC OF CHINA
PRODUCT NAME:	Multi-channel ECG
MODEL NUMBER:	EM-301、EM-302、EM-601、EM-602、EM-1201、EM-1202、EM-1203、EM-1204
UMDNS CODE:	11411
CLASSIFICATION - *ANNEX IX*:	class IIa, rule 10
CONFORMITY ASSESSMENT ROUTE:	MDD 93/42/EEC Annex II excluding (4)

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: SEE THE LIST OF STANDARDS

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	**0123**
(EC) CERTIFICATE(S):	**G1 073649 0010 Rev.01**
EC REP European Representative:	Well Kang Limited The Black Church, St. Mary's Place, Dublin 7, Ireland

START OF CE-MARKING: 2011-11-9

PLACE, DATE OF DECLARATION: *SHENZHEN P.R.C., 2019-12-05*

SIGNATURE: Jielin. Xie 2019.12.5

NAME: JIELIN XIE

POSITION: MANAGEMENT REPRESENTATIVE