

**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:**

PC ECG

MODEL NUMBER:

PE-1201 、 PE-1201A

UMDNS CODE:

16231

CLASSIFICATION - ANNEX IX:

Class II a, 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****European Representative:**Wellkang Ltd
Enterprise Hub, NW Business Complex, 1 Beraghmore Rd.,
Derry, BT48 8SE, Northern Ireland, UK**START OF CE-MARKING:**

2013-1-25

PLACE, DATE OF DECLARATION:

SHENZHEN P.R.C., 2021 - 5 - 13

SIGNATURE:

NAME: JIELIN XIE

POSITION: MANAGEMENT REPRESENTATIVE