DECLARATION OF CONFORMITY

ACCORDING TO THE MEDICAL DEVICES DIRECTIVE 93/42/EEC



Manufacturer:

PanSW Med Corp Limited

5th Floor C1 building Kemulang Industrial Park, Guangzhou, China

Product:

Cable/Leads, ECG (UMDNS code 15-754)

Classification:

Class I , rule according to Annex IX of the MDD

Conformity assessment route:

Annex VII

The undersigned hereby declares that the medical device as specified above confirms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC(MDD).

All supporting documentation is retained at the premises of the manufacturer.

Standards applied: see the list of the standards for which documented evidence of compliance can be provided.

AAMI/ANSI EC53:1995(R)2001 &AAMI/ANSI EC53A:1998(R)2001

ISO10993:2003e -1,-5,-10

IEC60101-1:1990

Place, Date of Issue Signature:

Guangzhou, 2020-08-11

Gang Liu General Manager

