

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

