



Verification of Conformity

With European Directives

Name: JIANGSU SAIKANG MEDICAL CO., LTD.

Add.: No.35 Lehong Road , Modern Agriculture Demonstration Park , Zhangjiagang City , Jiangsu Province , China

Product Name / Model or type:

Medical Pendant SK-P series Single arm pendant, double arm pendant, bridge pendant, used for terminal transfer of oxygen supply, suction, compressed air, nitrogen and other medical gases in the operating room.

Monitor SK-EM series Medical use monitor, various indicators used to monitor patients.

ECG SK-EM series Record changes in patient's heart activity for treatment.

Syringe Pump SK-EM series Syringe pump, infusion pump, for liquid injection.

Suction Device SK-EX series Electric suction unit, manual section unit, sputum suction unit.

The submitted sample of the above product has been tested for CE marking according to the following European Directives:

Medical Devices Regulation: 2017/745 / EU MDR

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485: 2016 ; EN ISO 14971: 2019 ; EN ISO 15223-1: 2016

EN 1041: 2008 ; EN 60601-1: 2005+A1: 2012 ; EN 60601-1-2: 2015

The referred report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). Regulation 2017/745 / EU on Medical Devices (MDR), ANNEX VII

The CE marking as shown below can be affixed on the product.

Certificate No.: AV-JSSK20210318037

Date: Mar 18 ,2021



for amtre veritas:

General Manager

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