

EU Declaration of Conformity

Manufacturer: Shanghai Yuechen Medical Supply Co., Ltd.
Building 1, Building 3, No.50, Majiazhai Road, Fengxian District,
Shanghai, China

SRN: CN-MF-000016968

EC Representative: Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherlands

SRN: NL-AR-000002066

Product Name: Disposable ECG electrodes

Trade name: Disposable ECG electrodes

Intended purpose: This product is the ECG acquisition device accessory, use with the equipment, the intentions of electrical monitoring and detection.

Models: HS01,HS02,HS03,HS04,HS05,HS06,HS07,HS08,HS09,HS10,HS11,HS12, HS13,HS14,HS15,HS16,HS17,HS18,HS19,HS20,WS01,WS02,WS03,WS04,WS05,WS06,WS07,WS08,WS09,WS10,WS11,WS12,WS13,WS14,WS15, WS16,WS17,WS18,WS19,WS20,TS01,TS02,TS03,TS04,TS05,TS06,TS07,TS08,TS09,TS10,TS11,TS12,TS13,TS14,TS15,TS16,TS17,TS18,TS19,TS20,HD 01,HD02,HD03,HD04,HD05,HD06,HD07,HD08,HD09,HD10,HD11,HD12 ,HD13,HD14,HD15,HD16,HD17,HD18,HD19,HD20,HM01,HM02,HM03, HM04,HM05,HM06,HM07,HM08,HM09,HM10,HM11,HM12,HM13,H M14,HM15,HM16,HM17,HM18,HM19,HM20,HA01,HA02,HA03,HA04, HA05,HA06,HA07,HA08,HA09,HA10,HA11,HA12,HA13,HA14,HA15,HA 16,HA17,HA18,HA19,HA20,HW01,HW02,HW03,HW04,HW05,HW06,H W07,HW08,HW09,HW10,HW11,HW12,HW13,HW14,HW15,HW16,H W17,HW18,HW19,HW20

Basic UDI-DI: 647145774HS1T3, 647145774WS1VE, 647145774TS1UX,
647145774HD1RN, 647145774HM1SH, 647145774HA1RD,
647145774HW1TF

Classification (According to the Annex VIII of MDR): Class I, Rule 1

Conformity assessment procedure: Annex II + Annex III of MDR

We herewith declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EU regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

Regulation:

Regulation (EU) 2017/745 on medical devices

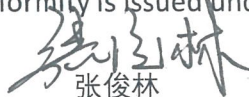
Standards:

EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 20417:2021, EN ISO 15223-1:2021, EN 62366-1:2015+A1:2020, EN ISO 10993-1:2020, EN ISO 10993-5-2009, EN ISO 10993-10:2023

The EU declaration of conformity is issued under the sole responsibility of manufacturer.

Signature:

Name:


张俊林

Function of person signed: General Manager

On behalf of: Shanghai Yuechen Medical Supply Co., Ltd.

Place: Shanghai, China

Date of issue: June 2, 2023