

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Shenzhen Creative Industry Co., Ltd.
1001, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, 518055
Shenzhen, PEOPLE'S REPUBLIC OF CHINA
CN-MF-000009430**

SRN (Manufacturer) **CN-MF-000009430**

Name and address of Authorized Representative: **Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg GERMANY
DE-AR-000000001**

SRN (EU Authorised) **DE-AR-000000001**

We declare that the product concerned has been designed and manufactured under a quality management system according to Regulation(EU) MDR 2017/745 Article 120, Annex II of 93/42/EEC and Regulation (EU) 2023/607

Medical Device: **Easy ECG Monitor
Model: PC-80B/Prince 180B/CARDIO-B
62641**

GMDN **62641**

Risk class: **Class IIa**

Basic UDI-DI **69419006PC80BS01JB**

Conformity assessment procedure: **93/42/EEC Annex II excluding(4)**

The EU declaration of conformity is issued under sole responsibility of the manufacturer. We hereby declare that the above mentioned products meet the provisions of the following EUROPEAN PARLIAMENT AND OF THE COUNCIL Regulation and Applicable standards. All supporting documents are retained under the premises of the manufacturer.

Regulations **MDR 2017/745 Article 120
93/42/EEC
Regulation (EU) 2023/607**

Applicable CS or Standard(s) **EN 60601-1: 2006+A1: 2013+A2:2021
EN 60601-1-2: 2015+A1:2021
EN 60601-1-11:2015+A1:2020
EN 60601-2-47:2015
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-23:2021
EN ISO 14971:2019+A11:2021
EN ISO 15223-1:2021
EN ISO 20417:2021**

Certificate No.: **G1 049076 0016 Rev.03; CL 049076 0017 Rev.01**

Issue date: **2021-04-26**

Expiry date: **2028-12-31**

Notified Body: **TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München, Germany**

Shenzhen, 2025/09/30
Place, date



Zhang Xiang Management Representative
Name and function