



REGISTRATION NO. 04719Q10000749

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

Registered Address: #380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China

Manufacturing Address: #380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, development, manufacturing, and service of Full Digital Colour Doppler Ultrasonic Diagnostic System, All-Digital Ultrasound Diagnostic System, Multi-Parameter Patient Monitor, Holter Systems, Ambulatory Blood Pressure Monitor, Digital 18-Lead Electrocardiograph, 18-Lead Electrocardiograph, Pediatric Electrocardiograph, Digital Multi-Channel Electrocardiograph, Digital ECG Workstation Software, ECG Data Management System Software, Digital Ultrasound Workstation Software, Central Monitor System Software, Handheld Ultrasound Diagnostic Instrument. The Design, development of PC ECG, Color Doppler Ultrasound System.

Date of issue: April 08, 2019

Date of expiry: April 07, 2022

Date of change: April 29, 2021

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**