

REGISTRATION NO. 04721Q10550R5M

### CERTIFICATE

## **OF QUALITY MANAGEMENT SYSTEM**

This is to certify that the quality management system of

#### Contec Medical Systems Co., Ltd.

Registered Address: No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, P.R.China

Manufacturing Address: No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, P.R.China

Has been assessed and conformed to the following standard(s) GB/T 19001-2016 idt ISO 9001:2015

#### The certificate is valid for the following scope:

The Design, Development, Production and Service of Digital Brain Electric Activity Mapping, Electrocardiograph, B Model Ultrasound Diagnostic Equipment, Patient Monitor, Ultrasonic Doppler Fetal Heartbeat Detector, Doppler Fetal Monitor, Pulse Oximeter, Patient Monitor System, Dynamic ECG System, Dynamic EEG System, ECG Workstation, Medical Image Workstation, Electronic Sphygmomanometer, Ambulatory Blood Pressure Monitor, Multi-parameters Vital Signs Monitor, Sleep Apnea Screen Meter, Portable ECG Monitor, Maternal/Fetal Monitor, Semi-auto Biochemistry Analyzer, Spirometer, Urine Analyzer, Infusion pump, Oxygen concentrator, Arteriosclerosis Detector, Compressor Nebulizer, ECG cable, SpO2 Simulator, NIBP Simulator, Multiparameter Simulator, Home-care Oxygen Generator, Infrared Thermometer, Mesh Nebulizer, Automatic Hematology Analyzer, Immunofluorescence Quantitative Analyzer, Specific Protein Analyzer, Automatic Biochemistry Analyzer, CUFF, Mouthpiece, Syringe Pump, SpO2 Assistant, Electronic Thermometer, Ambulatory Multi-paratemer Recorder, Str ess ECG Analysis System, Stethoscope.

> Date of issue: December 11,2021 Date of expiry: December 10,2024

**General Manager:** 

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





中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5<sup>th</sup> floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993



**REGISTRATION NO. 04721Q10000622** 

# CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

#### Contec Medical Systems Co., Ltd.

Registered Address: No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, P.R.China Manufacturing Address: No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, 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, Production and Service of Digital Brain Electric Activity Mapping, Electrocardiograph, B Model Ultrasound Diagnostic Equipment, Patient Monitor, Ultrasonic Doppler Fetal Heartbeat Detector, Doppler Fetal Monitor, Pulse Oximeter, Patient Monitor System, Dynamic ECG System, Dynamic EEG System, ECG Workstation, Medical Image Workstation, Electronic Sphygmomanometer, Ambulatory Blood Pressure Monitor, Multi-parameters Vital Signs Monitor, Sleep Apnea Screen Meter, Portable ECG Monitor, Maternal/Fetal Monitor, Semi-auto Biochemistry Analyzer, Spirometer, Urine Analyzer, Infusion pump, Oxygen concentrator, Arteriosclerosis Detector, Compressor Nebulizer, ECG cable, SpO2 Simulator, NIBP Simulator, Multiparameter Simulator, Home-care Oxygen Generator, Infrared Thermometer, Mesh Nebulizer, Automatic Hematology Analyzer, Immunofluorescence Quantitative Analyzer, Specific Protein Analyzer, Automatic Biochemistry Analyzer, CUFF, Mouthpiece, Syringe Pump, SpO2 Assistant, Electronic Thermometer, Ambulatory Multi-paratemer Recorder, Str ess ECG Analysis System, Stethoscope.

Date of issue: December 11,2021

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General Manager:

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

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5<sup>th</sup> floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993