



证书编号: 04721Q10550R5M

质量管理体系认证证书

兹证明

康泰医学系统（秦皇岛）股份有限公司

（统一社会信用代码：91130300601108025E）

住 所：秦皇岛市经济技术开发区秦皇西大街 112 号

生产地址：秦皇岛市经济技术开发区秦皇西大街 112 号

质量管理体系符合：

GB/T 19001-2016 idt ISO 9001:2015

体系覆盖：

数字脑电地形图仪，心电图机，B 型超声诊断设备，病人监护仪，超声多普勒胎儿心率仪，超声多普勒胎儿监护仪，脉搏血氧仪，中央监护系统软件，动态心电图仪，动态脑电图仪，心电工作站，医学影像工作站，臂式电子血压计，动态血压监护仪，多参数生命体征监测仪，睡眠呼吸初筛仪，便携式心电图计，胎儿/母亲多参数监护仪，半自动生化分析仪，肺功能仪，尿液分析仪，输液泵，医用制氧机，动脉硬化检测仪，医用压缩式雾化器，心电导联线，血氧模拟仪，无创血压模拟仪，多参模拟仪，家用制氧机，医用红外体温计，网孔式雾化器，血细胞分析仪，荧光免疫定量分析仪，特定蛋白分析仪，全自动生化分析仪，血压袖带，咬嘴，注射泵，血氧心电设备数据管理软件，无线医用电子体温计，动态生命体征参数监测仪，运动负荷心电检测仪，听诊器，新型冠状病毒抗原检测试剂（仅供出口），肺功能定标桶，睡姿训练仪，生命体征模拟仪，血氧模拟仪模拟手指，智能心电通用测试信号源，彩色多普勒超声诊断系统(仅供出口)，一次性肺功能仪用过滤嘴的设计开发，生产和服务。

肌电/诱发电位图仪的设计开发。

颁证日期：2021 年 12 月 11 日

有效期至：2024 年 12 月 10 日

换证日期：2023 年 01 月 03 日

总经理：

李朝晖

北京国医械华光认证有限公司



中国认可

国际互认

管理体系

MANAGEMENT SYSTEM

CNAS C047-M

注：认证组织需通过年度监督审核后，此证书方为持续有效。本证书信息可在国家认证认可监督管理委员会官方网站（<http://www.cnca.gov.cn>）或北京国医械华光认证有限公司网站（<http://www.cmdc.com.cn>）上查询。地址：北京市东城区安定门外大街甲 88 号中联大厦第 5 层 邮编：100011 电话：010-62351993



证书编号: 04721Q10000622

医疗器械 质量管理体系认证证书

兹证明

康泰医学系统（秦皇岛）股份有限公司

（统一社会信用代码：91130300601108025E）

住 所：秦皇岛市经济技术开发区秦皇西大街 112 号

生产地址：秦皇岛市经济技术开发区秦皇西大街 112 号

质量管理体系符合：

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖：

数字脑电地形图仪，心电图机，B 型超声诊断设备，病人监护仪，超声多普勒胎儿心率仪，超声多普勒胎儿监护仪，脉搏血氧仪，中央监护系统软件，动态心电图仪，动态脑电图仪，心电工作站，医学影像工作站，臂式电子血压计，动态血压监护仪，多参数生命体征监测仪，睡眠呼吸初筛仪，便携式心电图计，胎儿/母亲多参数监护仪，半自动生化分析仪，肺功能仪，尿液分析仪，输液泵，医用制氧机，动脉硬化检测仪，医用压缩式雾化器，心电导联线，血氧模拟仪，无创血压模拟仪，多参模拟仪，家用制氧机，医用红外体温计，网孔式雾化器，血细胞分析仪，荧光免疫定量分析仪，特定蛋白分析仪，全自动生化分析仪，血压袖带，咬嘴，注射泵，血氧心电设备数据管理软件，无线医用电子体温计，动态生命体征参数监测仪，运动负荷心电检测仪，听诊器，新型冠状病毒抗原检测试剂（仅供出口），肺功能定标桶，睡姿训练仪，生命体征模拟仪，血氧模拟仪模拟手指，智能心电通用测试信号源，彩色多普勒超声诊断系统(仅供出口)，一次性肺功能仪用过滤嘴的设计开发，生产和服务。

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总经理：

李朝晖

北京国医械华光认证有限公司





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-parameter Recorder, Stress ECG, Analysis System, Stethoscope, SARS-CoV-2 Antigen Rapid Test(Only for export), Calibration Syringe, Sleeping position training instrument, Vital Signs Simulator, SpO₂ Simulator Probe, Universal Multiparameter Simulator, Color Doppler Ultrasound Diagnostic System(Only for export), Respiratory Filter.

The Design, Development of EMG/EP System.

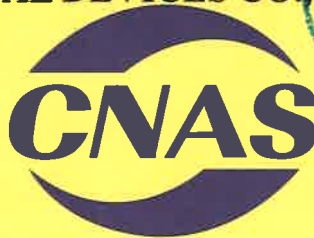
Date of issue: December 11, 2021

Date of expiry: December 10, 2024

Date of change: January 03, 2023

General Manager:

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



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.cnea.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th 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- parameter Recorder, Stress ECG, Analysis System, Stethoscope, SARS-CoV-2 Antigen Rapid Test(Only for export), Calibration Syringe, Sleeping position training instrument, Vital Signs Simulator, SpO₂ Simulator Probe, Universal Multiparameter Simulator, Color Doppler Ultrasound Diagnostic System(Only for export), Respiratory Filter.

The Design, Development of EMG/EP System.

Date of issue: December 11,2021

Date of expiry: December 10,2024

Date of change: January 03,2023

General Manager:

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



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