



Product Service

Certificate

No. Q5 050972 0053 Rev. 02

Holder of Certificate: **Contec Medical Systems Co., Ltd.**
 No.112 Qinhuang West Street
 Economic & Technical Development Zone
 066004 Qinhuangdao, Hebei Province
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production, Sales and Servicing of Dynamic EEG Systems, Dynamic ECG Systems, Digital Brain Electric Activity Mapping, Patient Monitor, Patient Monitor System, B-Ultrasound Diagnostic System, Electrocardiograph, ECG Workstation, Fetal Monitor, Ventilator, Pulse Oximeter, Pocket Fetal Doppler, Maternal/Fetal Monitor, Infusion Pump, Spirometer, Ambulatory Blood Pressure Monitor, Electronic Sphygmomanometer, EMG/EP System, Pulse Oximeter Probe, ECG Electrode Cable And Accessories, NIBP Cuff, Portable ECG Monitor, Semi-auto Biochemistry Analyzer, Urine Analyzer, Oxygen concentrator, Multi-parameter Vital Signs Monitor, Sleep apnea screen meter, Arteriosclerosis Detector, Compressor Nebulizer, Wearable Monitor, Electronic Thermometer, Mesh Nebulizer, Capnograph, Infrared Thermometer, Portable Phlegm Suction Unit, Positive Airway Pressure Devices, Insect bite helper, Color Doppler Ultrasound Diagnostic System, Blood Glucose Monitoring System.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_050972_0053_Rev.02

Report No.: BJ25090203

Valid from: 2026-03-04

Valid until: 2028-03-01

Date, 2026-03-04

Christoph Dicks
 Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Contec Medical Systems Co., Ltd.**
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Development Zone, 066004 Qinhuangdao, Hebei Province,
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See Scope of Certificate