DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 050972 0053 Rev. 00

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:

tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Sales, Installation and Servicing of Dynamic EEG Systems, Dynamic ECG Systems, Digital Brain Electric Activity Mapping, Patient Monitor, Patient Monitor System, B-Ultrasound Diagnostic System, ECG Recorder, ECG Workstation, ECG Monitor System, Medical Image Workstation, Fetal Monitor, Ventilator, Anesthetic Machine, High Frequency Surgical Unit, Pulse Oximeter, Pocket Fetal Doppler, Visual Stethoscope, Electric Suction Apparatus, Transcranial Doppler Analysis System, Maternal/Fetal Monitor, Infusion Pump, Spirometer, Ambulatory Blood Pressure Monitor, Electronic Sphygmomanometer, EMG/EP System, Pulse Oximeter Probe, Temperature Probe, ECG Electrode Cable And Accessories, Blood Pressure Cuff, Portable ECG Monitor, Semi-auto Biochemistry Analyzer, Urine Analyzer, Oxygen concentrator, Multi-parameter Vital Signs Monitor, Remote ECG Monitor, Sleep apnea screen meter, Arteriosclerosis Detector, Compressor Nebulizer, Wearable Monitor, Predictive Thermometer, Mesh Nebulizer, Capnograph and Infrared Thermometer.**

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 and certification regulation of 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. 00

Report No.: BJ21090203
Valid from: 2022-03-02
Valid until: 2025-03-01

Date, 2022-02-24

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD
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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

See Scope of Certificate

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