



Certificate

No. Q5 050972 0052 Rev. 01

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, 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, Ultrasonic Pocket 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.

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

Certificate

No. Q5 050972 0052 Rev. 01

requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1890204

Valid from: 2019-03-08

Valid until: 2022-03-01

Date, 2019-03-08



Stefan Preiß

Certificate

No. Q5 050972 0052 Rev. 01

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

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT