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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 050972 0058 Rev. 00

Manufacturer:

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

SRN Manufacturer - CN-MF-000007715

Authorized Representative:

Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 050972 0058 Rev. 00

Report No.: BJ22090201
Valid from: 2025-05-13
Valid until: 2030-05-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-05-13

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Certificate No. G15 050972 0058 Rev. 00

Classification:	Class IIa
Device Group:	MDA 0202 - Active non-implantable imaging devices utilising non-ionizing radiation
Classification:	Class IIa
Device Group:	MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters
Classification:	Class IIa
Device Group:	MDA 0204 - Other active non-implantable devices for monitoring and/or diagnosis
Classification:	Class IIa
Device Group:	MDA 0307 - Active non-implantable respiratory devices
Classification:	Class IIb
Device Group:	C900301 - PULSE OXIMETER SENSORS
Intended Purpose:	The Pulse Oximeter Probe can be used in measuring the pulse oxygen saturation and pulse rate.
Classification:	Class IIb
Device Group:	Z12159004 - OXYGEN CONCENTRATORS
Intended Purpose:	The device can be used in medical institutions for supplying oxygen.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Rev.	Dated	Report	Description
00	2025-05-13	BJ22090201	Initial issuance

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