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

Issue date: 2025-05-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

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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DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 ON MEDICAL DEVICES

CONTEC MEDICAL SYSTEMS CO., LTD.
No.112 Qinhuang West Street, Economic ＆Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE’S REPUBLIC OF CHINA

SRN of Manufacturer :CN-MF-000007715

EU REP

Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany

SRN of Authorised Representative:DE-AR-000005129

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
We keep all supporting documentation and ensure that the authorised representative has the necessary documentation permanently available.

Basic UDI-DI:	69450401CMS50DFG
Product and Trade Name:	Pulse Oximeter
EMDN Code:	Z1203020408
Catalogue Number/model:	CMS50D/CMS50DL
Risk Class of the Device:	Class IIa according to Annex VIII Rule 10

We, （CONTEC MEDICAL SYSTEMS CO., LTD.）herewith declare that the stated medical devices meet REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.
The harmonised standards and/or CS used and in relation to this conformity see annex.

NOTIFIED BODY:	TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany
NOTIFIED BODY IDENTIFICATION NUMBER:	0123
CONFORMITY ASSESSMENT PROCEDURE:	Regulation (EU) 2017/745, Annex IX excluding chapter II
(EC) CERTIFICATE(S):	G15 050972 0058 Rev. 00
PLACE, DATE OF ISSUE:	Qinhuangdao,2025/05/16
NAME AND FUNCTION, SIGNATURE:	HUKUN,Chairman/ manufacturer

DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 ON MEDICAL DEVICES

Appendix: list of (harmonised - EN) standards

No.	Standards	Title and Description
1	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices(ISO 14971:2019)
3	EN 60601-1:2006/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5	EN 60601-1-11:2015/A1:2021	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
6	EN ISO 80601-2-61:2019	Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
7	EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
8	EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
9	EN 62304:2006/A1:2015	Medical device software-Software life-cycle processes
10	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
11	ISO 15223-1:2021/Amd 1:2025	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
12	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)