ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attestation of Conformity

No. ROHS 14 06 50972 029

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

Product: **Pulseoxymeter (Pulse oximeter)**

Model(s): **CMS50D, CMS50D1, CMS50E**

Parameters:

Rated Input Voltage :	3VDC (CMS50D, CMS50D1); 3.6-4.2VDC (CMS50E)
Rated Input Current :	<30mA (CMS50D, CMS50D1); 100mA (CMS50E)
Rated Power Input :	0.09VA (CMS50D, CMS50D1); 0.37VA (CMS50E)

Tested according to: EN 62321:2009

The product was tested according to the European Directive 2011/65/EU concerning RoHS.

Pb, Hg, Cd, Cr(VI), PBBs and PBDEs could not be detected over the limit defined by the European Directive 2011/65/EU.

This Attestation of Conformity confirms the compliance with the listed requirements on a voluntary basis. It refers only to the sample submitted and does not certify the quality or safety of the serial products. See also notes overleaf.

Test report no.: 68169142025202

615420

Date, 2014-06-11 (Mario Ma)

CE After preparation of the necessary technical documentation as well as the EU declaration of conformity the required CE marking can be affixed on the product. Other relevant directives have to be observed.

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

A1 / 04.11

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Pulse Oximeter, CMS50D
CLASSIFICATION - ANNEX IX:	Class IIb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex II excluding chapter 4

WE, (CONTEC MEDICAL SYSTEMS CO., LTD) HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 M NCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	G1 050972 0050 Rev.04
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2008-11-04 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2020-06-18
SIGNATURE:	President

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	IEC60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	IEC60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	IEC 60601-1-6:2013	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
4	IEC 60601-1-11:2015	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
5	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
6	ISO 80601-2-61：2017	Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
7	IEC 62304:2015	Medical device software-Software life-cycle processes