

**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 CMS50DL

CLASSIFICATION - ANNEX IX:

Class II b, 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 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER:

CE 0123

(EC) CERTIFICATE(S):

G1 16 06 50972 050

EC REP

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg Germany

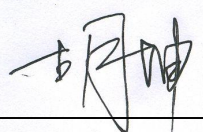
START OF CE-MARKING:

2010-09-30 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:

QINHUANGDAO, 2016-11-01

SIGNATURE:



President

TF-CE100106-09

Ver: H

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	IEC60601-1-2:2007	Medical electrical equipment- Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
2	IEC60601-1:2012	Medical electrical equipment- Part1: General requirements for basic safety and essential performance
3	EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
4	EN 62304:2006	Medical device software-Software life-cycle processes
5	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
6	ISO 80601-2-61: 2011	Medical electrical equipment —Part 2-61:Particular requirements for basic safety and essential performance of pulse oximeter equipment
8	IEC60601-1-11:2010	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