


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

<b>MANUFACTURER:</b>	<b>CONTEC MEDICAL SYSTEMS CO., LTD</b> No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
<b>MEDICAL DEVICE:</b>	Pulse Oximeter PO-100
<b>CLASSIFICATION - ANNEX IX:</b>	Class II b, Rule 10
<b>CONFORMITY ASSESSMENT ROUTE:</b>	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.	
<b>NOTIFIED BODY:</b>	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
<b>IDENTIFICATION NUMBER:</b>	<b>CE</b> 0123
<b>(EC) CERTIFICATE(S):</b>	<u>G1 050972 0050 Rev.04</u>
<b>EUROPEAN REPRESENTATIVE:</b>	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

**START OF CE-MARKING:** 2013-07-03 (Date or Lot or serial number)

<b>PLACE, DATE OF DECLARATION:</b>	QINHUANGDAO, 2020-06-18
<b>SIGNATURE:</b>	 _____ President

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


## Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN 60601-1-2:2007 (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	EN60601-1:1990+A1:1993+A2:1995 (IEC60601-1:1988+A1:1991+A2:1995)	Medical electrical equipment- Part 1: General requirements for safety
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
7	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

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

<b>MANUFACTURER:</b>	<b>CONTEC MEDICAL SYSTEMS CO., LTD</b> No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
<b>MEDICAL DEVICE:</b>	Pulse Oximeter PO-200
<b>CLASSIFICATION - ANNEX IX:</b>	Class II b, Rule 10
<b>CONFORMITY ASSESSMENT ROUTE:</b>	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.	
<b>NOTIFIED BODY:</b>	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
<b>IDENTIFICATION NUMBER:</b>	<b>CE</b> 0123
<b>(EC) CERTIFICATE(S):</b>	<u>G1 050972 0050 Rev.04</u>
<b>EUROPEAN REPRESENTATIVE:</b>	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

**START OF CE-MARKING:** 2013-07-03 (Date or Lot or serial number)

<b>PLACE, DATE OF DECLARATION:</b>	QINHUANGDAO, 2020-06-18
<b>SIGNATURE:</b>	 _____ President


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

NO.	Reference	Title
1	EN 60601-1-2:2007 (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	EN60601-1:1990+A1:1993+A2:1995 (IEC60601-1:1988+A1:1991+A2:1995)	Medical electrical equipment- Part 1: General requirements for safety
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
7	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

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

<b>MANUFACTURER:</b>	<b>CONTEC MEDICAL SYSTEMS CO., LTD</b> No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
<b>MEDICAL DEVICE:</b>	Pulse Oximeter PO-500
<b>CLASSIFICATION - ANNEX IX:</b>	Class II b, Rule 10
<b>CONFORMITY ASSESSMENT ROUTE:</b>	Annex II excluding chapter 4
<p>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.</p>	
<p>STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.</p>	
<b>NOTIFIED BODY:</b>	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
<b>IDENTIFICATION NUMBER:</b>	<b>CE</b> 0123
<b>(EC) CERTIFICATE(S):</b>	<u>G1 050972 0050 Rev.04</u>
<b>EUROPEAN REPRESENTATIVE:</b>	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

**START OF CE-MARKING:** 2013-07-03 (Date or Lot or serial number)

<b>PLACE, DATE OF DECLARATION:</b>	QINHUANGDAO, 2020-06-18
<b>SIGNATURE:</b>	 <hr style="width: 100%; border: 0.5px solid black;"/> President

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

NO.	Reference	Title
1	EN 60601-1-2:2007 (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	EN60601-1:1990+A1:1993+A2:1995 (IEC60601-1:1988+A1:1991+A2:1995)	Medical electrical equipment- Part 1: General requirements for safety
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
7	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