DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:	CONTEC MEDICAL SYSTEMS CO., LTD No.24 Huanghe West Road Economic & Technical Development Zone ,Qinhuangdao,Hebei Province, 066004,P.R.China
MEDICAL DEVICE:	Pulse Oximeter PO-100
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ.3

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 11 12 50972 017
EC REP EUROPEAN REPRESENTATIVE:	Shanghai International Trading Corp. GmbH(Hamburg) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2013-06-04 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:

SIGNATURE: President

CONTEC MEDICAL SYSTEMS CO.,LTD 秦皇岛市 康泰医学系统有限公司 QINHUANGDAO

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 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	EN60601-1-4:1996+A1:1999 (IEC60601-1-4:1996/A1:1999)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
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

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:	CONTEC MEDICAL SYSTEMS CO., LTD No.24 Huanghe West Road Economic & Technical Development Zone ,Qinhuangdao,Hebei Province, 066004,P.R.China
MEDICAL DEVICE:	Pulse Oximeter PO-200
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ.3

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
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EC REP EUROPEAN REPRESENTATIVE:	Shanghai International Trading Corp. GmbH(Hamburg) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2013-06-04 (Date or Lot or serial number)

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SIGNATURE: President

CONTEC MEDICAL SYSTEMS CO.,LTD 秦皇岛市康泰医学系统有限公司

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 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	EN60601-1-4:1996+A1:1999 (IEC60601-1-4:1996/A1:1999)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
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

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.24 Huanghe West Road Economic & Technical Development Zone ,Qinhuangdao,Hebei Province, 066004,P.R.China
MEDICAL DEVICE:	Pulse Oximeter PO-500
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ.3

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
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EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Trading Corp. GmbH(Hamburg) Eiffestrasse 80, 20537 Hamburg Germany

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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	EN60601-1-4:1996+A1:1999 (IEC60601-1-4:1996/A1:1999)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
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

DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.24 Huanghe West Road Economic & Technical Development Zone ,Qinhuangdao,Hebei Province, 066004,P.R.China
MEDICAL DEVICE:	Pulse Oximeter PO-300
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ.3

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
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DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Appendix: list of (harmonized - EN) standards

No.	Serial Number	Title and Description
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2	EN 60601-1-2: 2007	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility – Requirements and tests
3	EN 60601-1-4:1996+A1: 1999	Medical electrical equipment- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
4	EN 60601-1-6:2010 (IEC 60601-1-6:2010)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5	EN 60601-1-8:2007 (IEC 60601-1-8:2006)	Medical electrical equipment - Part 1-8: General requirements for basic safety essential performance- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
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	EN 60601-1-11:2010 (IEC 60601-1-11:2010)	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
8	EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices
9	EN 62304:2006 (IEC 62304:2006)	Medical device software - Software life-cycle processes

DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.24 Huanghe West Road Economic & Technical Development Zone ,Qinhuangdao,Hebei Province, 066004,P.R.China
MEDICAL DEVICE:	Pulse Oximeter PO-400
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ.3

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3	EN 60601-1-4:1996+A1: 1999	Medical electrical equipment- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
4	EN 60601-1-6:2010 (IEC 60601-1-6:2010)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5	EN 60601-1-8:2007 (IEC 60601-1-8:2006)	Medical electrical equipment - Part 1-8: General requirements for basic safety essential performance- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
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	EN 60601-1-11:2010 (IEC 60601-1-11:2010)	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
8	EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices
9	EN 62304:2006 (IEC 62304:2006)	Medical device software - Software life-cycle processes