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 Probe, ESA0008
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 1
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
EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2009-07-23 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2019-07-23
SIGNATURE:	President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	IEC60601-1:2012	Medical electrical equipment- Part 1: General requirements for safety
2	IEC60601-1-2:2014	Medical electrical equipment- Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	ISO 80601-2-61：2017	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use