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

MANUFACTURER:	MANUFACTURER NAME VOLUTARILY OBSCURED
MEDICAL DEVICE:	Pulse Oximeter, CMS50D
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ excluding chapter 4

WE, [redacted] 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.03
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, 2019-11-07
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 basic safety and essential performance
2	EN 60601-1-2:2007 (IEC60601-1-2:2007)	Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	EN 60601-1-6:2010 (IEC 60601-1-6:2010)	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
4	EN 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
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	EN 62304:2006	Medical device software-Software life-cycle processes