


**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>	Infrared Thermometer, TP500
<b>CLASSIFICATION - ANNEX IX:</b>	Class II a, Rule 10
<b>CONFORMITY ASSESSMENT ROUTE:</b>	Annex II excluding chapter 4
<b>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.</b>	
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 M NCHEN, 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:** 2020-06-18 (Date or Lot or serial number)

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

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

NO.	Reference No.	Title and Description
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
3	IEC60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	IEC60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5	IEC 60601-1-6:2013	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
6	IEC 62366-1:2016	Medical devices - Application of usability engineering to medical devices
7	ISO 80601-2-56:2017/Amd 1:2018	Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement — Amendment 1
8	IEC 62304:2015	Medical device software-Software life-cycle processes
9	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
10	EN 1041:2008	Information supplied by the manufacturer of medical devices
11	EN ISO ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements