


**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>	Capnograph,CA10M
<b>CLASSIFICATION - ANNEX IX:</b>	Class II a, 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/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE. THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.	
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>	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

<b>PLACE, DATE OF DECLARATION:</b>	QINHUANGDAO,2024/02/22
<b>SIGNATURE:</b>	 President

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

No.	Standards	Title and Description
1	ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	ISO 14971:2019	Medical devices - Application of risk management to medical devices
3	IEC 60601-1:2005 +AMD1:2012+AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	IEC 60601-1-2:2014 +AMD1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5	IEC 60601-1-6:2010 +AMD1:2013+AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6	ISO 80601-2-55:2018	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
7	ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
8	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
9	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
10	IEC 62366-1:2015 +AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
11	IEC 62304:2006 +AMD1:2015	Medical device software - Software life cycle processes
12	IEC 60601-1-8:2006+AMD1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems