

**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>	ECG cable , BIT0370
<b>CLASSIFICATION - ANNEX IX:</b>	Class I
<b>CONFORMITY ASSESSMENT ROUTE:</b>	Annex VII
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.	
<b>NOTIFIED BODY:</b>	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
<b>CE MARK:</b>	
<b>EUROPEAN REPRESENTATIVE:</b>	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany
<b>START OF CE-MARKING:</b>	<u>2010-03-20</u> (Date or Lot or serial number)
<b>PLACE, DATE OF DECLARATION:</b>	QINHUANGDAO, 2019-11-07
<b>SIGNATURE:</b>	 _____ President