


# 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>	Pulse Oximeter Probe, ESA0005
<b>CLASSIFICATION - ANNEX IX:</b>	Class II b, 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, 2024/04/01
<b>SIGNATURE:</b>	 _____ President