

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

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| <b>MANUFACTURER:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>CONTEC MEDICAL SYSTEMS CO., LTD</b><br>No.112 Qinhuang West Street, Economic & Technical<br>Development Zone, Qinhuangdao, Hebei Province,<br>PEOPLE'S REPUBLIC OF CHINA |
| <b>MEDICAL DEVICE:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Pulse Oximeter Probe, ESA0091                                                                                                                                               |
| <b>CLASSIFICATION - ANNEX IX:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Class II b, Rule 10                                                                                                                                                         |
| <b>CONFORMITY ASSESSMENT ROUTE:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Annex II excluding chapter 4                                                                                                                                                |
| <p>WE, (CONTEC MEDICAL SYSTEMS CO., LTD) HERewith DECLARE THAT THE STATED<br/>MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL<br/>DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;<br/>INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EC.<br/>ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.<br/>THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE<br/>MANUFACTURER.</p> |                                                                                                                                                                             |
| STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH<br>DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                             |
| <b>NOTIFIED BODY:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | TÜV SÜD PRODUCT SERVICE GMBH<br>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<br>Brehmstr. 56, 40239, Duesseldorf, Germany                                                                                                                   |

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| <b>PLACE, DATE OF DECLARATION:</b> | QINHUANGDAO, 2024/11/20                                                                                   |
| <b>SIGNATURE:</b>                  | <br>_____<br>President |