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

CONTEC MEDICAL SYSTEMS CO., LTD

MANUFACTURER: No.112 Qinhuang West Street, Economic & Technical

Development Zone, Qinhuangdao, Hebei Province,

PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: 3 in 1 Transducer,MPM1B30

CLASSIFICATION - ANNEX IX: Class II a, Rule 10

CONFORMITY ASSESSMENT ROUTE: 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 DEPLOY OF A 14 MAYS 1003 CONSERVING MEDICAL DEVICES.

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.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER: C € 0123

(EC) CERTIFICATE(S): <u>G1 050972 0050 Rev.04</u>

EUROPEAN REPRESENTATIVE: Prolinx GmbH

Brehmstr. 56, 40239, Duesseldorf, Germany

PLACE, DATE OF DECLARATION: QINHUANGDAO, 2025/08/29

SIGNATURE:

_President

TF-CE100915.1-09 Ver:K

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