DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	Beijing Demax Medical Technology Co., Ltd. A13-7,Jingshengnansi Street,Tongzhou District,101102 Beijing ,PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Name:*Disposable Pressure Transducer* MODEL CODE :*DPT1030,DPT1120,DPT1120NT,DPT1100M, DPT1120M,DPT1030B,DPT1120B,DPT1120NTA,DPT1100MA, DPT1120MA,DPT1120IB*
CLASSIFICATION - ANNEX IX:	Class Ⅱa, Rule 2,annex Ⅸ
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ.3

WE, （BEIJING DEMAX MEDICAL TECHNOLOGY CO., LTD.） HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
WE AS THE MANUFACTURER ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: SEE ATTACHED LIST (APPENDIX I) OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY:	*TÜV SÜD Product Service GmbH* *Ridlerstraße 65, 80339 Munich, Germany*
IDENTIFICATION NUMBER:	*0123*
(EC) CERTIFICATE(S):	*G1 063599 0031 Rev.02*

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.12 12:15:55 EEST
Reason: MoldSign Signature
Location: Moldova

EC REP

EUROPEAN REPRESENTATIVE:	*Shanghai International Holding Corp. GmbH(Europe)* *Eiffestrasse 80, 20537 Hamburg GERMANY*
START OF CE-MARKING:	*2015.09.03* (Date Or Lot Or Serial Number)
PLACE, DATE OF DECLARATION:	*BEIJING ,2021-04-15*
SIGNATURE:	Name: HUAYING DAI Position: GENERAL MANAGER

APPENDIX Ⅰ

EN 556-1:2001/AC: 2006 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices

EN 1041:2008 Information supplied by the manufacture of medical devices

EN ISO 10993-1:2009/AC: 2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4:Selection of tests for interactions with blood

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity

EN ISO 10993-7 :2008/AC:2009 Biological evaluation of medical devices - Part 7-Ethylene oxide sterilization residuals

EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

EN ISO 10993-12:2012 biological evaluation of medical devices part 12 sample preparation and reference materilas

EN ISO 11135-1:2007 Sterilization of health-care products- Ethylene oxide - Part 1:Requirements for the development, validation and routine control of a sterilization process for medical devices

EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)

EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

EN ISO11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006) EN ISO 11737-1:2006/AC:2009

EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process EN ISO 13485: 2016/AC:2018 Medical devices- Quality management systems - Requirements for regulatory purposes

EN ISO 14971:2012 Medical devices –Application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements(ISO 15223-1:2016, Corrected version 2017-03)

EN 62366:2008 Medical devices part 1: Application of usability engineering to medical devices

MEDDEV 2.7/1: 2016 Clinical Evaluation: A Guide For Manufacturers And Notified Bodies Under Directives 93/42/EEC And 90/385/EEC

EN 60601-1:2006/A1:2013Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)

EN 60601-1-2:2015 Medical electrical equipment-Part1-2:General requirements for basic safety and essential performance-Collateral Standard :Electromagnetic disturbances-Requirements and tests (IEC 60601-1-2:2014)