

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING 2007/47/EC) CONCERNING MEDICAL DEVICES



MANUFACTURER:

BEIJING TARGET MEDICAL TECHNOLOGIES INC.
NO. 60, SHUNREN RD., SHUNYI DISTRICT, BEIJING, 102200, P.R. CHINA
TEL.: 86 10-89493813/2512 FAX: 86 10-89419091/80120615

MEDICAL DEVICE:
UMDNS CODES

DISPOSABLE BLOOD PRESSURE TRANSDUCER
16615

CLASSIFICATION - ANNEX IX:

CLASS II B, RULE 10, ANNEX IX, MDD

CONFORMITY ASSESSMENT ROUTE: ANNEX II EXCLUDING(4)

WE, BEIJING TARGET MEDICAL TECHNOLOGIES INC. HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC (INCLUDING 2007/47/EC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

EN ISO 13485:2016+A11:2021; EN ISO 14971:2019+A11:2021; EN ISO 20417:2021 ;
EN ISO 15223-1:2021; EN 60601-2-34:2014; EN 60601-1:2006/A1:2013; EN 60601-1-2:2015;
EN ISO 10993-1:2020; EN ISO 10993-4:2017; EN ISO 10993-5:2009;
EN ISO 10993-7:2008/A1:2022; EN ISO 10993-10:2023; EN ISO 10993-11:2018;
EN ISO 11135:2014/A1:2019; EN ISO 11138-2:2017; EN ISO 11607-1:2020/A11:2022;
EN ISO 11737-1:2018/A1:2021; EN ISO 11737-2:2020; EN ISO 80369-7:2021; EN 556-1:2001/AC:2006;
MEDDEV 2.7.1 REV4:2016; MEDDEV 2.12/1 REV.8; MEDDEV 2.12/2 REV.2 ;
IEC 62366-1:2015/A1: 2020; EN ISO 8536-4:2020; EN ISO 8536-10:2015;
EN ISO 11138-1:2017; EN ISO 14644-1:2015; EN ISO 14644-2:2015; EN ISO 14644-3:2019

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER
(EC) CERTIFICATE(S):

CE 0123
No. G1 073322 0018 REV. 01
VALID UNTIL: 2028-12-31



EUROPEAN REPRESENTATIVE:

LEPU MEDICAL (EUROPE) COOPERATIEF U.A.
ADD: ABE LENSTRA BOULEVARD 30, 8448 JB, HEERENVEEN,
THE NETHERLANDS. TEL: +31-515-573399, FAX:
+31-515-760020

PLACE, DATE OF DECLARATION:
SIGNATURE

BEIJING, May 21, 2021

Jianping Wang

MANAGEMENT REPRESENTATIVE: JIANPING WANG

MODEL AS BELOW
MMBPTSA20
MMBPTSA30

MMBPTSB20
MMBPTSB30

MMBPTSC20
MMBPTSC30