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

MANUFACTURER:	Beijing Konted Medical Technology Co., Ltd, Room 111, Building 3, No. 27 , Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District,102629 Beijing, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Pocket Ultrasound System (C10) （C10MC,C10MX,C10MS,C10MB,C10XS,C10CS,C10RS,C10LC, C10MR,C10UE,C10UC,C10HQ,C10MT,C10RLpro,C10MQ, C10QC,C10QR,C10TC,C10XC,C10MTpro,C10MXpro,C10MSpro, C10MRpro,C10MBpro,C10XLpro,C10HL,C10H,C10QT,C10TS,C10T, C10CX,C10CT,C10CL,C10SN,C10LN,C10RN,C10RA,C10L,C10R, C10RL,C10UR,C10RQ,C10RC,C10TX,C10C,C10B,C10S,C10PL,C10P, C10CW,C10XL,C10UL,C10）
CLASSIFICATION - ANNEX IX:	IIa
CONFORMITY ASSESSMENT ROUTE:	MDD Annex II, without chapter 4

WE, Beijing Konted 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 OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; AND MDR ARTICLE 120(3) OF PROVISIONS INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: (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:	CE 0123
(EC) CERTIFICATE(S):	NO. G2 003973 0002 Rev.01
EC REP **EUROPEAN REPRESENTATIVE:**	*SUNGO Europe B.V. Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands*

START OF CE-MARKING: 2019.04.29
UNTIL OF CE-MARKING: 2028.12.31

PLACE, DATE OF DECLARATION: BEIJING, MARCH24, 2023

SIGNATURE: President
Sam Liu