

**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)

CLASSIFICATION - ANNEX IX:

Ila

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; 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:

SHANGHAI INTERNATIONAL HOLDING CORP. GMBH
(EUROPE) EIFFESTRA E 80 20537 HAMBURG GERMANY

START OF CE-MARKING:

2019.04.29

UNTIL OF CE-MARKING:

2023.08.05

PLACE, DATE OF DECLARATION:

BEIJING, APRIL 29, 2019

SIGNATURE:


Sam Liu

President

