Declaration of Conformity

Manufacturer: WuHan Youkey Bio-Medical Electronics Co., Ltd.

No.3, 6F,Unit 1, North Building of Xingye Building, Science and Technology Park of Wuhan University, University Park Road, East Lake Development District,

Wuhan City, Hubei Province, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg GERMANY

Product: Pocket Ultrasound System (UMDNS:14276)

Model: D8

Supplementary information: Included are following transducers: C5-2Ks, C5-2Fs, L11-4Ks,

L11-4Gs, E10-4Ks, C8-5Ks.

Classification: | | a (According to Rule 10 of MDD Annex | X)

Conformity Assessment Route: MDD Annex II. Without chapter 4

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device. All supporting documentations are retained under the premises of the manufacturer. WuHan Youkey Bio-Medical Electronics Co., Ltd. is exclusively responsible for Doc.

Notified Body: TÜV SÜD Product Service GmbH

Ridlerstraße 65

D- 80339 Münich, Germany.

Notified Body No.: 0123

Certificate: G1 17 04 98396 002 The Certificate is valid until 2022-09-03

Start of CE-Marking:2017-09-04 First Certificate: G1 17 04 98396 002

Place, Date of Issue: Wuhan, 2017-09-04

Signature:

Name of Authorized Signature: Mr. Ligang Hu (胡立钢)
Position Held in Company: Management Representative