Digitally signed by Perminov Andrei
Date: 2024.02.07 17:23:26 EET
Reason: MoldSign Signature
Location: Moldova

EC Declaration of Conformity

Manufacturer:

Chison Medical Technologies Co., Ltd.

No.3 Changjiang South Road,
Xinwu District, Wuxi, 214028
Jiangsu, P.R. China
No.9, Xinhuihuan Road, Xinwu District,
Wuxi, Jiangsu, China 214028

whose single Authorized Representative:

Shanghai International Holding
Corp.GmbH(Europe)
Eiffestrasse 80,20537Hamburg,Germany
DIMDI NO.:DE/0000040627

We, the manufacturer, herewith declare that the products

Ultrasound Diagnostic Systems

Model: SonoTouch10, SonoTouch20, SonoTouch30, SonoTouch50, SonoTouch60, SonoTouch 80, ECO 1, ECO 2, ECO 3, ECO 4, ECO 5, ECO 6, ECO 1 EXPERT, ECO 2 EXPERT, ECO 3 EXPERT, ECO 4 EXPERT, ECO 5 EXPERT, ECO 6 EXPERT, QBit 1, QBit 2, QBit 3, QBit 4, QBit 5, QBit 6, QBit 7, QBit 8, QBit 9, QBit 10, QBit 11, QBit 12, EBit 10, EBit 20, EBit 30, EBit 40, EBit50, EBit60, EBit70, EBit80, EBit 90, SonoBook1, SonoBook2, SonoBook3, SonoBook4, SonoBook5, SonoBook6, SonoBook 7, SonoBook 8, SonoBook 9, CBit 1, CBit 2, CBit 3, CBit 4, CBit 5, CBit 6, CBit 7, CBit 8, CBit 9, CBit 10, XBit 20, XBit 30, XBit 40, XBit 50, XBit 60, XBit 70, XBit 80, XBit 90, SonoEye P1, SonoEye P2, SonoEye P3, SonoEye P5, SonoEye P6, SonoAir 10, SonoAir 20, SonoAir 30, SonoAir 40, SonoAir 50, SonoAir 60, SonoAir 70

UMDNS-Code: **15976**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex II of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60147775 0001
Issue date: 03,04.2020
Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

CHISON MEDICAL TECHNOLOGIES CO.,LTD 无锡祥生医疗科技股份有限公司 国际部 INTERNATIONAL DEPT.

10.05.2023

Liu Qifei