EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Chison Medical Technologies Co., Ltd.

Shanghai International Holding Corp.GmbH(Europe)

No.228, ChangJiang East Road, Block 51 and 53, Phase 5, Shuofang Industrial Park, Xinwu District, Wuxi, Jiangsu, China 214142 No.9, Xinhuihuan Road, Xinwu District,

Eiffestrasse 80,20537Hamburg,Germany DIMDI NO.:DE/000040627

Wuxi, Jiangsu, China 214028

We, the manufacturer, herewith declare that the products

Ultrasound Diagnostic Systems

Model:ECO 1,ECO 2,ECO 3,ECO 4,ECO 5,ECO 6,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,EBit 50,EBit 60,EBit 70,EBit 80,EBit 90,SonoBook 1,SonoBook 2,SonoBook 3,SonoBook 1,SonoBook 4,SonoBook 5,SonoBook 6,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

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

C € 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 se

Directive 93/42/EEC

21.04.2021

Conformity set out in Annex II of

言(科技股份有限公司)。

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