EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Chison Medical Technologies Co.,Ltd.

Shanghai International Holding Corp.GmbH(Europe)

No.3 Changjiang South Road, Xinwu District, Wuxi, 214028

Eiffestrasse 80,20537Hamburg,Germany DIMDI NO.:DE/0000040627

Jiangsu, P.R. China

No.9, Xinhuihuan Road, Xinwu District,

Wuxi, Jiangsu, China 214028

We, the manufacturer, herewith declare that the products

Ultrasound Diagnostic Systems

Model:SonoBook 8

Probe: L12-V

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 set out in Annex II of Directive 93/42/EEC.

12.05.2022

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Jiangsu, P.R. China

DIMDI NO.:DE/000040627

No.9, Xinhuihuan Road, Xinwu District,

Wuxi, Jiangsu, China 214028

We, the manufacturer, herewith declare that the products

Ultrasound Diagnostic Systems

Model: ECO 1 Probe: MC5V-A

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

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12.05.2022

Liu Qifei

TECHNOLOGIE