

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

Jiangsu, P.R. China

DIMDI NO.:DE/0000040627

No.9, Xinhuihuan Road, Xinwu District,
Wuxi, Jiangsu, China 214028

We, the manufacturer, herewith declare that the products
Ultrasound Diagnostic Systems

Model: SonoEye P2, SonoEye P3, SonoEye P5, SonoEye P6

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.

09.06.2022

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