EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Chison Medical Imaging Co., Ltd.

Shanghai International Holding Corp.GmbH(Europe)

No.228, ChangJiang East Road,

Eiffestrasse 80,20537Hamburg,Germany

Block 51 and 53. Phase 5 Industrial Park.

DIMDI NO.:DE/0000040627

ShuoFang, New District, Wuxi 214142, China

No.9 Xin Hui Huan Road, New District,

WuXi, P.R.China

We, the manufacturer, herewith declare that the products

Digital Ultrasound Diagnostic System

Model: ECO 1, ECO 2, ECO 3EXPERT, ECO 5, SonoTouch 30, i3, i8, i9, Q5, Q9, QBit 7, QBit 9,

EBit 60

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.: HD600929090001

Issue date: 22,04.2014 Expiry date: 14.11.2017

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive

93/42/EEC.

06.24. 2016