

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

CHISON Medical Technologies Co., Ltd.
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,
Wuxi, Jiangsu, China 214028

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: 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

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.: HD60123652 0001

Issue date: 15.11.2017

Expiry date: 14.11.2022

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

8.8.2019

Liu Qifei

