EC Declaration of Conformity

Manufacturer:

CHISON Medical Technologies Co.,Ltd.
No.3 ChangJiang South Road,Xinwu District, Wuxi,Jiangsu, China 214028
SRN:CN-MF-000021605

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80,20537Hamburg, Germany
DIMDI NO.:DE/0000040627

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product name	Digital Color Doppler Diagnostic System
Model	SonoAir 10, SonoAir 20, SonoAir 30, SonoAir 40, SonoAir 50, SonoAir 60, SonoAir 70, SonoAir 80, SonoAir 90
Intended Purpose	The SonoAir Series Digital Color Doppler Ultrasound System is intended for diagnostic ultrasound imaging in B(2D),B/M,M,B+CFM,B+CPA (PD),B+DPD,B+PW,B+ CFM + D (PW), B+ CPA(PD) + D (PW),TDI and Fusion Harmonic Imaging modes. The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified clinician for evaluation of Fetal ,Abdominal, Pediatric, Small Organ (breast, thyroid, testes),Adult Cephalic, Cardiac Adult, Musculo-skeletal (Conventional , Superficial), Peripheral Vascular, Trans-vaginal and Urology.
Risk Class	Class IIa per rule 10 of Annex VIII to Medical Device Regulation (EU) 2017/745.

We, the manufacturer, herewith declare that the product in this declaration of conformity (DoC) is in conformity with regulations, Directives, Common specifications, and standards as followings:

EU Regulation and Directive	• REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

	• Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. • Directive 2006/42/EU of the European Parliament and of the Council of 17 May 2006 on the machinery and amending Directive 95/16/EC(recast)
Standards and Common Specifications	EN 60601-1:2006+ A1:2013+A2:2021 EN 60601-1-6:2010+ A1:2015+A2:2021 EN 62366-1:2015 IEC 62304:2006+A1:2015 EN 60601-2-37:2008+A1:2015 IEC 62366:2007 + A1:2014 EN 60601-1-2:2014+A1:2021 ISO 10993-1: 2018 EN ISO 14971:2021 EN ISO15223-1:2021 EN 1041:2008+A1: 2013 EN 62366:2008

Compliance of the designated product with the Medical Device Regulation 2017/745 [MDR] has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

CE 0197

Note that the Notified Body number does not apply to the 2011/65/EU (restriction of the use of certain hazardous substances in electrical and electronic equipment) Directive and Radio Equipment Directive 2014/53/EU.

Place, Date of Issue: WuXi China, Sep 30,2022

Signature (signed for and on behalf of CHISON): Liu Qifei

Name: Mr. Liu Qifei

Position: Regulatory Affairs Manager