Digitally signed by Furculiță Andrei
Date: 2022.12.28 11:04:31 EET
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shenzhen Shimai Medical Equipment Co., Ltd.
East, Floor 5, Building B5, area B, Yinlong industri
No.292 Shenshan Road, Baolong Street
Longgang District
518116 Shenzhen
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Digital Color Doppler Diagnostic Scanners with Electronic Transducers.

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-03-02
Certificate Registration No.:	SX 60145724 0001
An audit was performed. Report No.:	17054666 002
This Certificate is valid until:	2022-11-26

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-03-02

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel : +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland®

Registration No.: DD 60145723 0001

Report No.: 17054666 002

Manufacturer:
Shenzhen Shimai Medical
Equipment Co., Ltd.
East, Floor 5, Building B5, area B, Yinlong industrial city
No.292 Shenshan Road, Baolong Street
Longgang District
518116 Shenzhen
P.R. China

Products:
Digital Color Doppler Diagnostic Scanners with Electronic Transducers.

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-03-02

Date: 2020-03-02

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

第二类医疗器械经营备案凭证

备案号：粤深食药监械经营备 20181088 号

企业名称	深圳市时迈医疗设备有限公司
住　　所	深圳市龙岗区宝龙街道深汕路 292 号银龙工业城 B 区 B5 栋 5 楼东
经营场所	深圳市龙岗区宝龙街道深汕路 292 号银龙工业城 B 区 B5 栋 5 楼东
库房地址	深圳市龙岗区宝龙街道深汕路 292 号银龙工业城 B 区 B5 栋 5 楼东
法定代表人	蔡成琳
企业负责人	王俊
经营方式	批零兼营
经营范围	全部二类医疗器械（不含体外诊断试剂）

备案部门（公章）

备案专用章

备案日期：2018 年 06 月 11 日

营业执照

统一社会信用代码 91440300MA5F4UFH8Q

名　　称　深圳市时迈医疗设备有限公司

类　　型　有限责任公司

住　　所　深圳市龙岗区宝龙街道深汕路292号银龙工业城B区B5栋5楼东

法定代表人　蔡成琳

成立日期　2018年05月17日

重要提示

1、商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。

2、商事主体经营范围和许可审批项目等有关事项及年报信息和其他信用信息，请登录深圳市市场和质量监督管理委员会商事主体信用信息公示平台（网址http://www.szcredit.org.cn）或扫描执照的二维码查询。

3、商事主体须于每年1月1日-6月30日向商事登记机关提交上一年度的年度报告。商事主体应当按照《企业信息公示暂行条例》等规定向社会公示商事主体信息。

登记机关　深圳市市场监督管理局

2018 年 05 月 17 日

中华人民共和国国家工商行政管理总局监制