

## CERTIFICATE

### **ATTESTATION** CERTIFICATE OF ELECTROMAGNETIC COMPATIBILITY DIRECTIVE

Technical file of the company mentioned below has been observed and audit has been completed successfully.

2014/30/EU Electromagnetic Compatibility Directive has been taken as references for these processes

Company Name

: Jiangsu Suhong Medical Instruments Co., Ltd.

Company Address

: Industrial Zone, Xueyan Town, Wujin District, Changzhou City,

Jiangsu Province, China

Related Directives and Annex : Electromagnetic Compatibility 2014/30/EU

Related Standards

: EN 55014-1:2006+A1:2009+A2:2011

Product Name

: Weighing Scale

Report No and Date

: ESC-JSSH-201709-01A

Product Brand/Model/Type

: RGZ-10,RGZ-20,RGZ-50,RGZ-120,RGZ-150,RGZ-160,RGZ-200, RGT-10,RGT-50,RGT-140,RGT-160,RGT-200,RCS-20,RCS-200

Certificate Number

: M.2017.201.N1952

Initial Assessment Date

:01.09.2017

Registration Date

Reissue Date/No

: 04.09.2017

**UDEM** International Certification **Auditing Training Centre Industry** 

and Trade Inc. Co.

The validity of the certificate can be checked through www.udem.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

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REGISTRATION NO. 04718Q10000118

# CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

JIANGSU SUHONG MEDICAL INSTRUMENTS CO., LTD.

Registered Address: Industrial Zone, Xueyan Town, Wujin District

Postcode: 213100

Manufacturing Address: Industrial Zone, Xueyan Town, Wujin District

Has been assessed and conformed to the following standard(s)
YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of visual acuity charts stretchers reflector lamps x-ray film viewers manual wheelchairs weighing scales electronic weighing scales electronic infant scales infant height beds electronic infant height beds sitting height gauges mobility scooters walking aids crutchs medical kit for home visits mobile ultraviolet rays sterilization truck for design developments production and service.

Date of issue:March 23,2018
Date of expiry:March 22,2021

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.



### Conformity Declaration to the European Norms 93/42/CEE, 2007/47/CEE for Medical Devices

We, JIANGSU SUHONG MEDICAL INSTRUMENTS CO.,LTD, registred addres: Industrial Zone, Xueyan Town, Wujin District, Changzhou .City Postcode: 213169, MANUFACTURER the following items:

Weighing scales: <u>RGZ-10</u>; <u>RGZ-20</u>; <u>RGZ-50</u>; <u>RGZ-120</u>; <u>RGZ-150</u>; <u>RGZ-160</u>; <u>RGZ-200</u> <u>RGT-10</u>; <u>RGT-50</u>; <u>RGT-140</u>; <u>RGZ-160</u>; <u>RGT-200</u>; <u>RCS-20</u>; <u>RCS-200</u>

SH-8039 Stretcher (ISO13485)

#### DECLARE

that the item inside the boxes is included in Medical Devices Class I and REP no. 42689, and it is marked CE and it is realized in accordance with the European Norms 93/42/CEE and 2007/47/CEE

Best regards,

Suny

江苏苏宏医疗器械有限公司 JIAMESU SUMONE MEDICAL INSTRUMENTS CO. LED

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