



**No. Q5 17 08 71993 015**

No.8, Tongxing Road  
Economic & Technical Development Area  
226010 Nantong, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

Little Doctor Electronic ( Nantong ) Co., Ltd.  
No.8, Tongxing Road, Economic & Technical  
Development Area, 226010 Nantong, Jiangsu,  
PEOPLE'S REPUBLIC OF CHINA



tuv-sud.com/ps-cert

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

otînga Stela



Digitally signed by Pottinga Stela  
Date: 2019.02.13 15:55:37 EET  
Reason: MoldSign Signature  
Location: Moldova



**TÜV®**



乐道克电子制造（南通）有限公司  
LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.

No. 8 Tongxing Road  
Economic and Technical  
Development Area  
Nantong Jiangsu  
P.R. of China  
Tel.: +86 0513 85986718

## Declaration of Conformity

Manufacturer: **LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.**  
Address: No. 8 Tongxing Road, Economic and Technical Development  
Area, Nantong, Jiangsu, P.R. China

EU Representative: **LITTLE DOCTOR EUROPE SP. Z O. O.**  
**(st. Zawila 57G, 30-390 Krakow, Poland)**

Product: Aneroid Sphygmomanometer and Accessories  
Model Code: **LD-71**

Classification (MDD, Annex IX): **IIa**

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directive and Standards. All supporting documentation are retained under the premise of manufacturer and the notify body.

### Directives

General Applicable Directives: The COUNCIL DIRECTIVE 93/42/EEC concerning Medical  
Devices (MDD 93/42/EEC)

Standards: ISO13485:2003 and all applicable harmonized standards  
(published in the Official Journal of the European  
Communities).

Notified Body: TÜV SUD Product Service GmbH  
Zertifizierstelle Ridlerstrabe, 65 80339 Munchen, Germany

Certificate: G2M 16 04 71993 013

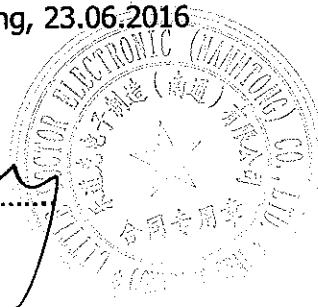
Expiration date of the Certificate: 15.06.2021

Data CE mark was affixed: June 2011

Place, Date: Nantong, 23.06.2016

Signature: .....  
Name: Pan Xinhua  
Position: General Manager

*Pan Xinhua*





Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Production Quality Assurance

### No. 19 0248 QS/NB

The quality system of manufacturer

**Wuxi Medical Instrument Factory Co., Ltd.**

**No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City,  
Jiangsu 214194 China**

has been certified as meeting the requirements of

**Directive 93/42/EEC**  
**on medical devices, Annex V**

for the following product category(ies):

**Mercury free clinical thermometer**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with the conformity of the devices with metrological requirements. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

**Valid from:** 2019-05-22  
**Valid until:** 2024-05-21  
**First Issued:** 2019-05-22  
**Revision:** -



Date: 2019-05-22

**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

**Annex to EC Certificate No. 19 0248 QS/NB**  
issued for manufacturer:

**Wuxi Medical Instrument Factory Co., Ltd.**  
**No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City,**  
**Jiangsu 214194 China**

**Product(s):**


<b>Name:</b>	<b>Mercury free clinical thermometer</b>
<b>Trade name(s):</b>	Mercury free clinical thermometer
<b>Model(s):</b>	CR.W00
<b>Class:</b>	Im
<b>GMDN:</b>	34343

**Facility(ies):**

Wuxi Medical Instrument Factory Co., Ltd.  
No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City, Jiangsu 214194 China



Date: 2019-05-22  
Revision: -

  
**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



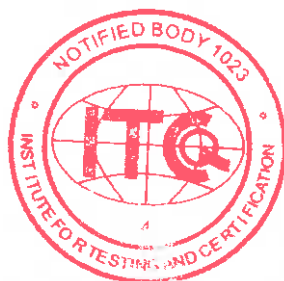
Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

**Annex to EC Certificate No. 19 0248 QS/NB**  
issued for manufacturer:

**Wuxi Medical Instrument Factory Co., Ltd.**  
**No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City,**  
**Jiangsu 214194 China**

**Certificate History:**

Revision	Date	Reference Number	Action
	2019-05-22	803602800	Certification



Date: 2019-05-22  
Revision: -

**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023





We cover  
credibility 

QSCert, spol. s r. o.  
Certification Body of Management Systems  
Residence address: Klimentska 1746/52, Nove Mesto, 110 00 Prague 1, Czech Republic  
Postal address: Strazska cesta 7892, 960 01 Zvolen, Slovak Republic

by this

# CERTIFICATE

certifies that the Quality Management System of

## PJSC "Steklopribor"

18, Ozerna str., Zavodske, Lohvytsky district, Poltava region, 37240, Ukraine

has been established and duly implemented and company applies it in accordance with  
the standard

## ISO 9001:2008

provisions for the following areas:

**Design, development, production and sales of technical thermometers and  
accessories thereof, hydrometers, hygrometers, vacuum manometers,  
domestic thermometers, measuring and laboratory glassware**

Certified location: 18, Ozerna str., Zavodske, Lohvytsky district, Poltava region, 37240, Ukraine

On the basis of certification audit, protocol No. R 037/16/39 it was proven that the management  
system meets the requirements of the above listed standard.

Certificate No.: Q-5497/16

Initial certification date: 01.12.2004

Date of issue: 15.11.2016

Expiry date: 04.11.2019

Expiry date of certificate is conditioned by successful completion of transition audit according to ISO 9001:2015 until  
14.09.2018.

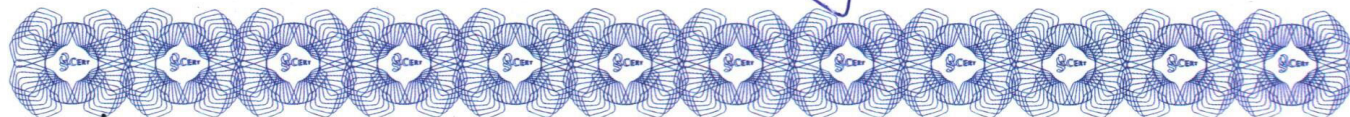


S 3177



This certificate is valid only if it is published  
among valid certificates on [www.qscert.com](http://www.qscert.com)

Ing. Marcel Šluch  
chief executive







Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

No. G2 17 07 63744 016

### Manufacturer:

**Wenzhou Rising Industrial Co., Ltd**

No.345, Xincheng Road, Wenzhou  
325000, China

### EC-Representative:

**Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

### Product

### Category(ies):

Silicone/SEBS/PVC Manual Resuscitators  
(Including Mask, Positive End-Expiratory Pressure Valve,  
Oxygen Tube, Reservoir Bag, Mouth opener,  
Oropharyngeal airway, Manometer),  
Resuscitation Mask, Continuous Positive Airway Pressure  
Mask/Non-invasive Ventilation Mask, Simple Oxygen Mask,  
Venturi Mask, Non-Rebreathing Mask,  
Aerosol Mask w/Nebulizer,  
Breathing Circuit (Including Mask,  
Elbow Connector, Y piece, Corrugate Tubing,  
Collapsible Tubing, Water Trap, Straight Connector, HMEF),  
Anesthesia Circuit (Including Mask, Elbow Connector  
w/Luer port & cap, Y piece, Corrugate Tubing,  
Collapsible Tubing, Straight Connector, Breathing Bag,  
Bacterial Filter, gas sampling line),  
Laryngeal Mask Airway, Anesthesia Mask



The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

SH17176EXT01

Valid from:

2017-10-01

Valid until:

2022-09-30

Date, 2017-08-01

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2

# Certificate of Registration



The Governing Board of  
Q.A. International Certification Limited  
hereby grants to:

**SURGICON (PVT) LTD**

Registration No.: QAIC / PK / 889 - B

*(hereinafter called the Registered Company) the right to be listed in the Directory of Registered Companies in respect of the services listed below. These services shall be offered by the Registered Company at or from only the address given below in accordance with the quality management system in Compliance with the Requirements of **ISO 13485:2016**.*

Address to which this Certificate refers:

**P.O. Box: No: 244, Khadim Ali Road, Sialkot - Pakistan**

Approved Scope to which this Certificate refers:

**Manufacture of Non-Active Surgical and Dental Instruments.**

(Please note that the above scope represents the certified activity of the named organisation and as such, the organisation may undertake additional activities that are not covered under this certification).

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

**Certificate Issue Date:** 1st April 2019 - **Certificate Renewal Before:** 31st March 2020  
**Date of Initial Registration:** 28th April 2006 - **Re-Certification Before:** 31st March 2021

This Certificate of Registration is granted subject to the Regulations approved by the Board.

**QA INTERNATIONAL**

Q.A. International Certification Ltd.  
Dudley Court  
Dudley Road  
Darlington  
United Kingdom  
DL1 4GG

Tel: +44 (0)1325 384272  
Fax: +44 (0)1325 480980  
www.qai.co.uk



The use of the Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 046.



# CERTIFICATE



**Registration No. DCS/9479903**

Application of Council Directive 93/42/EEC as updated directive 2007/47/EC for Class I  
Medical Devices

This is certifying that the products submitted are:

**CLASS I MEDICAL DEVICES  
(Re-Useable, Non-Powered Surgical Instruments)**

Manufactured By:

**SURGICON LTD**

**P.O. Box: No. 244, Khadim Ali Road, Sialkot-Pakistan**

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive  
2007/47/EC for Class I Medical Devices

The Technical file of the products have been assessed according to the procedure of  
Conformity Assessment described in the Annex -I, Annex VII.

**Limitations:**

The manufacturer must inform DCS of any substantial changes occurred in the Product or  
process in order to examine whether this certificate remains valid. Conformance to all the  
regulatory requirements is the sole responsibility of the manufacturer including the appointment  
of EU Authorized Representative and registration with concerned competent authority

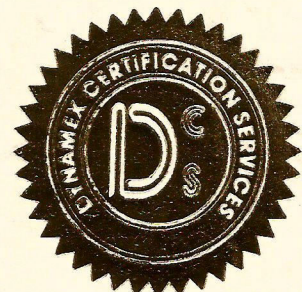
CHAIRMAN

SCHEME MANAGER

Issue Date: 09 April, 2019

Expiry Date: 08 April, 2020

[www.dynamexcertification.org](http://www.dynamexcertification.org)





## ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ

### ОАО «Объединение Альфапластик»

наименование организации или фамилия, имя, отчество индивидуального предпринимателя, принявших декларацию о соответствии

Межрайонная инспекция ФНС РФ № 46 по г. Москве

Основной государственный регистрационный номер 1027739807501 от 27.02.2007

сведения о регистрации организации или индивидуального предпринимателя (наименование регистрирующего органа, дата регистрации, регистрационный номер)

ИНН 7718059469

107150, Россия, г. Москва, 4-й проезд Подбельского, д. 3

тел.: (499)160-22-11

адрес, телефон, факс

в лице генерального директора Д.В. Берсенева

должность, фамилия, имя, отчество руководителя организации, от имени которой принимается декларация

заявляет, что Кружка Эсмарха резиновая КР-«Альфа»

код ОКП 25 3720

ТУ 9398-037-00149535-2006

Производства ОАО «Объединение Альфапластик» (107150, г. Москва, 4-й проезд Подбельского, д. 3, Россия)

#### Серийный выпуск

наименование, тип, марка продукции (услуги), на которую распространяется декларация, код ОК 005-93 и (или) ТН ВЭД СНГ или ОК 002-93 (ОКУН), сведения о серийном выпуске или партии (номер партии, номер изделий, реквизиты договора /контракта/, накладная, наименование изготовителя, страны и т.п.)

#### соответствуют требованиям

ГОСТ Р ИСО 10993-1-2009, ГОСТ Р ИСО 10993-5-2009, ГОСТ Р ИСО 10993-10-2009, ГОСТ Р ИСО 10993-11-2009, ГОСТ Р ИСО 10993-12-2009, ГОСТ Р 52770-2007

обозначение нормативных документов, соответствие которым подтверждено данной декларацией, с указанием пунктов этих нормативных документов, содержащих требования для данной продукции

#### Декларация принята на основании:

Протокол испытаний ИЛ «Токсиколог» (РОСС RU.0001.21ИМ55)

№ 00203 от 16.06.2016

информация о документах, являющихся основанием для принятия декларации

Дата принятия декларации

10.11.2016

Декларация о соответствии действительна до

09.11.2021

М.П.



подпись

Д.В. Берсенева

инициалы, фамилия

#### Сведения о регистрации декларации о соответствии

Орган по сертификации продукции "ВНИИС" Открытого акционерного общества

"Всероссийский научно-исследовательский институт сертификации"

123557, г.Москва, Электрический пер., д.3/10, стр.1

тел.:(499) 253-34-58, факс:(499) 253-77-13

наименование и адрес органа по сертификации, зарегистрировавшего декларацию



№ РОСС RU.АЯ12.Д01523 от 10.11.2015

дата регистрации и регистрационный номер декларации

подпись

В. Я. Тимко

инициалы, фамилия руководителя ОС