CERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 08 71993 015

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

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Aneroid sphygmomanometers, Blood pressure monitor, Nebulizer, Stethoscopes, Dental oral irrigator, Examination light Production and distribution of Digital thermometer**

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1740414

Valid from: 2017-10-12
Valid until: 2020-09-30

040527686511181

Date, 2017-10-12

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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: Address:	**LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.** 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: Model Code:	Aneroid Sphygmomanometer and Accessories **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

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):

Name:	**Mercury free clinical thermometer**
Trade name(s):	Mercury free clinical thermometer
Model(s):	CR.W00
Class:	Im
GMDN:	34343

Facility(ies):

Wuxi Medical Instrument Factory Co., Ltd.

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

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2019-05-22
Revision: -

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

QSCert

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, Lokhvytsky 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, Lokhvytsky 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.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

S 3177

CERTIFICATION BODY QSCert OF MANAGEMENT SYSTEMS

This certificate is valid only if it is published among valid certificates on www.qscert.com

Ing. Marcel Šlúch
chief executive

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 Indstrial 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

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

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

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. _____ **Д.В. Берсенев**
подпись 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

М.П. _____ **В. Я. Тимко**
подпись инициалы, фамилия руководителя ОС