ЦИОНАЛЬНАЯ СИСТЕМА ПОДТВЕРЖДЕНИЯ СООТВЕТСТВИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

ГОССТАНДАРТ

№ 0011763

Серия **Б**

СЕРТИФИКАТ СООТВЕТСТВИЯ

Зарегистрирован в реестре
№ BY/112 03.06. 048 00023
Срок действия с **22 июля 2015 г.** по **22 июля 2020 г.**

Орган по сертификации Республиканское унитарное предприятие "Центр экспертиз и испытаний в здравоохранении", 220037, г. Минск, Товарищеский переулок, 2а, тел. 299-53-49, 299-53-50

Настоящий сертификат удостоверяет, что идентифицированная должным образом продукция изготовленная Открытое акционерное общество "Гродненский завод торгового машиностроения", Республика Беларусь

и представленная на сертификацию под наименованием Коробки стерилизационные круглые с фильтрами КСКФ-3, КСКФ-6, КСКФ-9, КСКФ-12, КСКФ-18 ТУ РБ 500059647.020-2002
СЕРИЙНОЕ ПРОИЗВОДСТВО

код ОКП РБ – 33.10.14.000
код ТН ВЭД – 8419 20 000 0

соответствует требованиям технических нормативных правовых актов:
ГОСТ 20790-93, ТУ РБ 500059647.020-2002 (изм. "3")

Заявитель (изготовитель, продавец) Открытое акционерное общество "Гродненский завод торгового машиностроения", Республика Беларусь, 230023, г. Гродно, ул. Тимирязева, 16

код УНП – **500059647**

Сертификат выдан на основании:

а) документов регистрационного удостоверения № ИМ-7.5617/0903 от 22.04.2005, сертификата соответствия на систему менеджмента качества № BY/112 05.01.021 1004 от 06.09.2007

б) протоколов испытаний испытательной лаборатории "Торгмаш" (BY/112 02.2.0.1553) № 219 от 16.07.2009.

Инспекционный контроль осуществляет за стабильностью функционирования системы менеджмента качества осуществляет орган по сертификации продукции, услуг, систем управления "ПОЛИТЕХ-СЕРТ"

Особые отметки

Дополнительная информация

М.П.

Руководитель органа по сертификации — **А.Ю.Столяров**
подпись, инициалы, фамилия

Эксперт-аудитор — **И.И. Панкевич**
подпись, инициалы, фамилия

НАЦИОНАЛЬНАЯ СИСТЕМА ПОДТВЕРЖДЕНИЯ СООТВЕТСТВИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

БГЦА	BY/112 021.03
BSCA	СТБ ISO/IEC 17021-1

Орган по сертификации систем менеджмента «ПОЛИТЕХ-СЕРТ»
Филиала БНТУ «Научно-исследовательская часть»
пр. Независимости, 65, комн. 239, 220013, г. Минск, Республика Беларусь,
адрес места осуществления деятельности: ул. Я.Коласа, 12, комн. 1002А,
220013, г. Минск, Республика Беларусь

СЕРТИФИКАТ СООТВЕТСТВИЯ

СТБ ISO 9001

Зарегистрирован в реестре под **№ BY/112 05.01. 021 06955**

Дата регистрации 23 июля 2018 г.
Действителен до 23 июля 2021 г.

Настоящий сертификат соответствия выдан

Открытому акционерному обществу
«Гродненский завод торгового машиностроения»

УНП 500059647
Республика Беларусь, 230023,
г. Гродно, ул. Тимирязева, 16

и удостоверяет, что система менеджмента качества

производства торгово-технологического и вспомогательного оборудования, водонагревателей и электроводонагревателей, гидроаккумуляторов автоматизированных, установок вентиляционных, шкафов сушильных, сушилок для обуви, контейнеров и форм для сыра, коробок круглых металлических и тележек грузовых и универсальных

соответствует требованиям СТБ ISO 9001-2015

Заведующий
НИИЛ транспортных средств БНТУ А.Б.Дмитриев

№ 0023413

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

EC Certificate

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

Registration No.: DD 60106307 0001

Report No.: 15089783 001

Manufacturer:

Shanxian Runte Medical
Instruments Co., Ltd.
Nanduan Wenhua Road, Shanxian,
274300 Heze City, Shandong
China

Products:

- Disposable Suture Needles with Non-absorbable Threads
- Sterile Syringe for Single Use
- Sterile Infusion Sets for Single Use
- Disposable Lancets for Blood Specimen Collection

Replaces Approval, Registration No.: DD 60034791 0001

Expiry Date: 2020-11-23

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: 2015-11-24

Date: 2015-11-24

Notified Body
TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
X. Ren

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.

EC Certificate

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

Registration No.: DD 60112728 0001

Report No.: 15095315 001

Manufacturer:
Changzhou ZhongYou Medical
Device Co., Ltd.
Wugang, Zhenglu Town
Changzhou
213115 Jiangsu
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60040100 0001

Expiry Date: 2021-07-28

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.

Notified Body

Effective Date: 2016-08-08

Date: 2016-08-08

X. Ren

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60112728 0001
Report No.: 15095315 001

Manufacturer:
Changzhou ZhongYou Medical Device Co., Ltd.
Wugang, Zhenglu Town
Changzhou
213115 Jiangsu
China

Products:
- Suction Catheters
- Stomach Tubes
- Feeding Tubes
- Mucus Extractors
- Urinary Catheters (Nelaton Catheters, Tiemann Catheters)
- Oxygen Masks
- Nebulizer Masks

For following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:
- Nasal Oxygen Cannulae
- Disposable Urine Drainage Bags
- Cervical Scrapers
- Medical Brushes
- Rectal Catheters
- Suction Connecting Tubes with Yankauer

Notified Body

Date: 2016-08-08

X. Ren

MEDICOR
MEDITŰ KFT.

Declaration of Conformity

The undersigned declares that the goods described below are manufactured

by our company (description of the goods, quantitiy. reference to the invoice.etc.):

Surgical needle (Annex l.)

Placeof production: MEDICOR MEDITŰ Kft H-6900 Makó, Rákos út 6.

Short description of the manufacturing procedure:

In accordance with technology no. MU-7147:

The country of origin of the goods: HUNGARY

and the goods fully comply with the requirements of the non preferential

rules of origin laid down in the articles 22-26 of the council regulation (CE)

No. 2913/92 (Community Customs Code) and/or Annex 10 or 11 to the council

regulation (EC) No. 2454/93 (Implementing Provisions of the Community Customs Code).

Moreover, these products are manufactured by a company certified under

ISO9001:2008, which products are classified as Class I. invasive devices by

the EÜM Decree No. 4/2009 (III.17.) implemented under Directives (EEC)

No. 93/42. (Annex No.9.III/2.2.6/b, of the Decree EÜM No. 4/2009.III.17.)

The undersigned declares that the infromation given above is true and correct.

He undetakes to provide any further proof to this declaration if required by

the Chamber of Commerce and Industry.

MEDICOR MEDITŰ
Sebészeti Varrótű Gyártó Kft.
6900 Makó, Rákosi út 6.
Adószám: 10471773-2-06

Makó 2018.02.06.

MEDICOR MEDITŰ Kft

6900 Makó,Rákosi út 6.

Csongor György

managing director

H-6900 Makó, Rákosi út 6.
Telefon /Fax: (62) 510-701
E-mail: meditu@invitel.hu
Internet: www.meditu.hu.

TÜVRheinland CERT ISO 9001

Manufacturer's Declaration

The undersigned declares that the goods described below are manufactured by our company (description of the goods, quantity, reference to the invoice, etc.):

Surgical needle,
Place of production: MEDICOR MEDITU Kft. H-6900 Makó, Rákosi út 6.

Short description of the manufacturing procedure:

In accordance with technology no. MU-7147:

The country of origin of the goods: Hungary

and the goods fully comply with the requirements of the non preferential rules of origin laid down in the articles 22-26 of the council regulation (EC) No. 2913/92 (Community Customs Code) and/or Annex 10 or 11 to the council regulation (EC) No. 2454/93 (Implementing Provisions of the Community Customs Code). Moreover, these products are manufactured by a company certified under ISO 9001:2008, which products are classified as Class I. invasive devices by the EÜM Decree No. 4/2009. (III.17.) implemented under Directives (EEC) No. 93/42. (Annex No.9. III/2.2.6/b. of the Decree EÜM No. 4/2009. (III.17.).

The undersigned declares that the information given above is true and correct.
He undertakes to provide any further proof to this declaration if required by the Chamber of Commerce and Industry.

MEDICOR MEDITŰ Kft.
6900 Makó, Rákosi út 6.

Makó, 2017.01.31.
MEDICOR MEDITŰ Kft.
6900 Makó, Rákosi út 6.

Csongor György
managing director

Place and date, company name and address

Name, position in company, signature

EC Certificate

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

Registration No.: DD 60136001 0001

Report No.: 15065241 009

Manufacturer:
Huaian Angel Medical Instruments Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60101257 0001

Expiry Date: 2024-01-26

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: 2019-01-27

Date: 2019-01-17

Notified Body

Herbert Zhong

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60136001 0001
Report No.: 15065241 009

Manufacturer: Huaian Angel Medical Instruments Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

Products:

- Disposable Suture Needles
- Disposable Surgical Blades & Scalpels with Plastic Handle
- Sterile Blood Lancets
- Surgical Instruments Kits

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Urinary Drainage Bags
- Disposable Umbilical Cord-Clamps

Notified Body

Date: 2019-01-17

Herbert Zhong

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle