En exécution du Règlement UE 2016/425 du Parlement Européen et du Conseil du 09 mars 2016 relatif aux équipements de protection individuelle et abrogeant la directive 89/686/CEE l'EPI objet de cette attestation est conforme aux exigences essentielles de santé et de sécurité applicables

In application of the Regulation EU 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/ECC, the PPE relative to this certificate is compliant with the essential health and safety requirements.

Aliénor Certification, organisme notifié pour effectuer l'examen UE de type prévu et identifié sous le numéro 2754 attribue
Alienor Certification, body notified to carry out the EU type examination and identified under number 2754, grants

l'ATTESTATION D'EXAMEN *UE* DE TYPE

the EU type Examination Certificate

N° 2754/2361/085/10/18/0742

au modèle d'équipement de protection individuelle suivant :
to the following designated personal protective equipment:

- Protection individuelle de l'œil : lunettes de protection
  Personal eye-protection : safety goggles ……..…....(dénomination)*(product)*
- JJI/**YSA2**……..…...……....(marque commerciale)*(trademark)*
- Unique *One size*……..……..(taille)*(size)*
- **JINHUA JINGLAN INDUSTRY & TRADE CO., Ltd.** Xiaoshun Town, Jindong District, Jinhua City, Zhejiang Province, P.R.CHINA…….……...(fabricant demandeur)*(manufacturer applicant)*
- **NF EN 166 :2002** ……..……....(référentiel technique)*(standard)*
- Type II……..……..……..……..……..……..(catégorie EPI)*(category)*

Date de début de validité *Date of beginning of validity*	Date de renouvellement *Date of renewal*	Date d'expiration *Expiration date*
26/10/2018	**/**	**25/10/2023**

Pour les EPI de catégorie III, cette attestation ne peut être utilisée qu'en liaison avec une des procédures de validation de la conformité visées à l'Article 19 point c) du règlement 2016/425.
For category III PPE, this certificate may only be used in conjunction with one of the conformity validation procedures referred to in Article 19 c) of Regulation 2016/425.

A Châtellerault, *In Châtellerault*

Alexandre ADALBERT-DEMARTAIZE
Président *President*

Signature numérique de Alexandre ADALBERT DEMARTAIZE
Date : 2018.10.26 11:56:05 +02'00'

Nota : toutes modifications du type apportées à l'EPI ou à sa documentation technique, approuvées par le fabricant et qui peuvent remettre en cause la conformité de l'EPI aux exigences essentielles de santé et de sécurité applicables ou aux conditions de validité de cette attestation doit être portée à la connaissance de l'organisme notifié conformément à l'annexe V point 7.2 du règlement UE 2016/425.
Any modification carried out on the material being the subject of the present EU type Examination Certificate, or on the technical documents, approved by the manufacturer and that could question the compliancy of the PPE with the essential health and safety requirements or the validy conditions of this certificate, must be brought to the attention of the notified body, in accordance with Annex V point 7.2 of Regulation UE 2016/425.

Cette attestation comporte 1 page. *This is a one page document.*

ALIENOR CERTIFICATION
ZA du Sanital – 21 Rue Albert Einstein - 86100 CHATELLERAULT - France
Tél : 33 (0)5 49 14 13 10 – Fax : 33 (0)5 49 21 76 20 Courriel : **contact@alienor-certification.fr** Site Internet : http://www.alienor-certification.fr

DECLARATION OF CONFORMITY

1) Manufacturer : KAZAN MEDICAL INSTRUMENTS PLANT JSC (KMIP JSC)
Address: No.12, Salikh Saidashev str., Kazan, 420021, Republic of Tatarstan, RUSSIA

2) European authorized representative: SKIRGESA JSC
Address: ENERGETIKU STR.8, LT-52461, KAUNAS, LITHUANIA
On product labels printed as:
SKIRGESA JSC, : ENERGETIKU STR.8, LT-52461, KAUNAS, LITHUANIA
FAX. +370 37458161, E-mail: info@skirgesa.lt

3) Product(s) *(name, type or model/batch number, etc.)*:

Barbed Broaches	TS 9434-083-05519988-2002 *see appendix*

4) The product(s) described above is in conformity with:
DIRECTIVES
General Applicable Directive:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 june 1993 Concerning medical device (MDD93/42/EEC)

Document No.	Edition / Date of issue
BS EN 62366	2008-04-30
EN ISO 14971:2012	2012-08-30
EN 1041:2008	2009-02 19
EN 1639:2009	2010-07-07
EN ISO 10993-11:2009	2009-12-02
EN ISO 17665-1:2006	2006-11-15

5) Additional information *(conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:
Conformity assessment procedure for CE-marking: Medical Device Directive, Annex VII

KAZAN, RUSSIA , 2017-05-19 ----------
(Place & date of issue (yyyy-mm-dd)) Shakirev Nur Khamzinovich, Director-General of KMIP JSC
(name, function and signature of manufacturer)

KAUNAS, LITHUANIA,2017-05-19 ----------
(Place & date of issue (yyyy-mm-dd)) SKIRMANTAS AKELIS, DIRECTOR of SKIRGESA JSC

(name; function and signature of authorized representative)

Appendix

Date: 2017-05-19

List of devices.

Device name	Type/ model/ref number	Risk class / rule[1]	First date of CE-compliance
Barbed Broaches length of 50 mm and 30 mm	340.600.909.202.020 340.600.909.202.025 340.600.909.202.030 340.600.909.202.035 340.600.909.202.040 340.600.909.202.050 340.600.909.202.060	Class I / Rule 5	2013-10-01
Barbed Broaches with attached handle, length of 35 mm	340.640.909.202.020 340.640.909.202.025 340.640.909.202.030 340.640.909.202.035 340.640.909.202.040 340.640.909.202.050 340.640.909.202.060	Class I / Rule 5	2013-10-01

[1] See risk classification in Medical Device Directive, annex IX

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2010/08019

от 02 ноября 2017 года

На медицинское изделие
Пульпоэкстракторы ПЭ-"КМИЗ" по ТУ 9434-083-05519988-2002

Настоящее регистрационное удостоверение выдано
Акционерное общество "Казанский медико-инструментальный завод" (АО "КМИЗ"), Россия,
420021, Республика Татарстан, г. Казань, ул. Салиха Сайдашева, д. 12

Производитель
Акционерное общество "Казанский медико-инструментальный завод" (АО "КМИЗ"), Россия,
420021, Республика Татарстан, г. Казань, ул. Салиха Сайдашева, д. 12

Место производства медицинского изделия
АО "КМИЗ", Россия,
420021, Республика Татарстан, г. Казань, ул. Салиха Сайдашева, д. 12

Номер регистрационного досье **№ РД-19747/57361 от 27.10.2017**

Вид медицинского изделия **336440**

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.13.190**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 02 ноября 2017 года № 9251
допущено к обращению на территории Российской Федерации

Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.Ю. Павлюков**

0036907

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60032905 0001

Report No.: 17016755 001

Manufacturer:
SHENZHEN SUPERLINE
TECHNOLOGY CO., LTD.
3/F, 3rd BLDG,
Meijing Industrial Park
Qiaoxiang Rd (west)

518053 Nanshan District, Shenzhen
China

Scope:
Manufacture of Orthodontic Wires, Dental Root-canal Instruments, Gutta-percha Points, Sterile Absorbent Paper Points

Replaces Approval, Registration No.: DD 60012354 0001

Date of Expiry: 08.10.2020

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Date 08.10.2015

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

En exécution du Règlement UE 2016/425 du Parlement Européen et du Conseil du 09 mars 2016 relatif aux équipements de protection individuelle et abrogeant la directive 89/686/CEE l'EPI objet de cette attestation est conforme aux exigences essentielles de santé et de sécurité applicables

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l'ATTESTATION D'EXAMEN *UE* DE TYPE

the EU type Examination Certificate

N° 2754/2361/085/10/18/0742

au modèle d'équipement de protection individuelle suivant :
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- **NF EN 166 :2002** ……..…….....(référentiel technique)*(standard)*
- Type II……..……..……..……..……..…..…..(catégorie EPI)*(category)*

Date de début de validité *Date of beginning of validity*	Date de renouvellement *Date of renewal*	Date d'expiration *Expiration date*
26/10/2018	**/**	**25/10/2023**

Pour les EPI de catégorie III, cette attestation ne peut être utilisée qu'en liaison avec une des procédures de validation de la conformité visées à l'Article 19 point c) du règlement 2016/425.
For category III PPE, this certificate may only be used in conjunction with one of the conformity validation procedures referred to in Article 19 c) of Regulation 2016/425.

A Châtellerault, *In Châtellerault*

Alexandre ADALBERT-DEMARTAIZE
Président *President*

Signature numérique de Alexandre ADALBERT DEMARTAIZE
Date : 2018.10.26 11:56:05 +02'00'

Nota : toutes modifications du type apportées à l'EPI ou à sa documentation technique, approuvées par le fabricant et qui peuvent remettre en cause la conformité de l'EPI aux exigences essentielles de santé et de sécurité applicables ou aux conditions de validité de cette attestation doit être portée à la connaissance de l'organisme notifié conformément à l'annexe V point 7.2 du règlement UE 2016/425.
Any modification carried out on the material being the subject of the present EU type Examination Certificate, or on the technical documents, approved by the manufacturer and that could question the compliancy of the PPE with the essential health and safety requirements or the validy conditions of this certificate, must be brought to the attention of the notified body, in accordance with Annex V point 7.2 of Regulation UE 2016/425.

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TÜV NORD

ZERTIFIKAT / *Certificate*

DIN EN ISO / EN ISO 13485 : 2016

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Yelatma Instrument Making Enterprise, JSC
Yelatma 391351, Yanina 25
Ryazan Region
Russia

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält.
Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.
This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / *Scope*

Entwicklung, Herstellung und Vertrieb von nicht sterilen IVD Einmalgefäßen und Behältnissen für die Desinfektion und Vorreinigung und elektromedizinisch therapeutischen und diagnostischen Geräten

Design, manufacturing and distribution of non sterile containers for IVD and containers for disinfection and pre-cleaning and electro medical devices for therapy and diagnostics

Reg.-Nr. / *Reg.-No.* 44 221 117836
Bericht Nr. / *Report No.* 3524 6418

Gültigkeit / *Validity*
von / *from* 2019-09-28
bis / *until* 2022-09-27
Edition 6

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-10-17

Die Gültigkeit kann unter https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank verifiziert werden.
Validity can be verified at https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-12007-05-01

COMPANY ELAMED SINCE 1980

NO 1 MANUFACTURER OF MEDICAL EQUIPMENT IN RUSSIA
RECOGNIZED WORLDWIDE

Tel: +7-4912-503-023, Web: www.elamed.com

DECLARATION OF CONFORMITY WITH DIRECTIVE 93/42 EEC FOR MEDICAL PRODUCTS

DESCRIPTION OF GOODS: POLYMERIC TANK-CONTAINERS FOR DISINFECTION AND PRE-STERILIZATION OF MEDICAL INSTRUMENTS

MODEL: EKaDH-0,1/01-"ELAT"; EKpDH-0,1/01-"ELAT"; EDPO-1-01; EDPO-3-01; EDPO-5-01; EDPO-10-01; EDPO-10D-01; EDPO-1S; EDPO-3S; EDPO-5S

MANUFACTURER'S NAME: JOINT STOCK COMPANY "YELATMA INSTRUMENT-MAKING ENTERPRISE"

Polymeric tank-containers for disinfection and pre-sterilization of medical instruments are classified in compliance with European Medical Device Directive 93/42/EEC as I Class Safety medical products.

The present declaration confirms that the tank-containers manufactured according to the technical documentation in compliance with Annex VII 93/42 EEC conform to essential requirements of MDD 93/42 EEC Annex 1 and the relevant standard EN ISO 13485:2012 and are entitled to have an CE mark.

Responsible body in EU: MK Touristenbetreuung & Medtechnik
76, Theodor-Heuss str. 51149, Cologne, Germany

Technical Director: Mr. A. Kadyrkov

Yelatma, Russia, the 17th of August, 2016

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