SZUTEST

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED- 1834001-D01

Manufacturer: **AKO MED d.o.o.**
Zdravka Celara 12, 11000 Belgrade, Serbia

Product(s): **Sterile Absorbable Surgical Sutures**

Model(s):
JOST PGA Quick
JOST PGLA Quick
JOST PGA
JOST PGLA
JOST PGCL
JOST PDO
JOST PDO Barbed

Reference Report No: MM0023-P001-R01, MM0023-P001-R03

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2023-12-05.

Issue Date: 2018-12-06

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi Akif İnan Sok. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED-1834001-D02

Manufacturer:	**AKO MED d.o.o.** Zdravka Celara 12, 11000 Belgrade, SERBIA
Product(s):	**Sterile Non-Absorbable Surgical Sutures**
Model(s):	JOST Polypropilen, JOST PVDF, JOST PTFE, JOST ePTFE, JOST Polyester, JOST UHMWPE, JOST Polyamide, JOST Silk
Reference Report No:	MM0023-P001-R01, MM0023-P001-R02, MM0023-P003-R01, MM0023-P003-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2023-12-05.

Issue Date:	2018-12-06
Revision No.:	01 Rev.
Revision Date:	2019-10-22

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Rukiye BALKAN
Deputy General Manager

This version of certificate has come into force on 23.03.2017. 1/1 2195-MED-1834001-D02 Rev.01

SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1834001

Manufacturer: **AKO MED d.o.o.**
Zdravka Celara 12, 11000 Belgrade, SERBIA

Product(s): **Sterile Absorbable & Non-Absorbable Surgical Sutures**

Model(s): Models For Sterile Absorbable Surgical Sutures
JOST PGA Quick, JOST PGLA Quick, JOST PGA, JOST PGLA, JOST PGCL, JOST PDO, JOST PDO Barbed

Models For Sterile Non-Absorbable Surgical Sutures
JOST Polypropilen, JOST PVDF, JOST PTFE, JOST ePTFE, JOST Polyester, JOST UHMWPE, JOST Polyamide, JOST Silk

Reference Report No: MM0023-P001-R01, MM0023-P001-R02, MM0023-P001-R03, MM0023-P003-R01, MM0023-P003-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2023-12-05.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Issue Date: 2018-12-06
Revision No.: 01 Rev.
Revision Date: 2019-10-22

Rukiye BALKAN
Deputy General Manager

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 32229101

AKO MED d.o.o.

Headquarter : Zdravka Čelara 12, 11000 Belgrade SERBIA

Production Address : Slovenski put bb, Jagodina SERBIA

EN ISO 13485:2016

Design, Production and Sales of Sterile Absorbable & Non-Absorbable Surgical Sutures

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date	18.10.2022
Expiry Date	15.03.2025

TÜRKAK BDS NO YS-B12F-FAFD

TÜRKAK

Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021
AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

BUREAU VERITAS
Certification

AKO MED d.o.o.

Zdravka Čelara 12, 11000 Belgrade, Serbia

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Production and distribution of medical devices, instruments and other medical equipment

Original cycle start date:	**21.07.2020**
Expiry date of previous cycle:	**NA**
Certification Audit date:	**25.05.2020**
Certification cycle start date:	**21.07.2020**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	**20.07.2023**

Certificate No.: **SL23559Q** Version: **01** Revision date: **21.07.2020**

BUREAU VERITAS Certification

UKAS MANAGEMENT SYSTEMS 0008

Certification body address: 5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom
*Local office: **Linhartova 49a, 1000 Ljubljana, Slovenia***

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please call: **+386 1 47 57 670**

BUREAU VERITAS
Certification

AKO MED d.o.o.

Zdravka Čelara 12, 11000 Belgrade, Serbia

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 14001:2015

Scope of certification

Production and distribution of medical devices, instruments and other medical equipment

Original cycle start date:	**29/01/2021**
Expiry date of previous cycle:	**NA**
Certification / Recertification Audit date:	**11/12/2020**
Certification / Recertification cycle start date:	**29/01/2021**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	**28/01/2024**

Certificate No.: **SL23847E** Version: **01** Revision date: **29/01/2021**

BUREAU VERITAS Certification

UKAS MANAGEMENT SYSTEMS

0008

Certification body address: 5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom
*Local office: **Linhartova 49a, 1000 Ljubljana, Slovenia***

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please call: **+386 1 47 57 670**

JAZMP
Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES OF THE REPUBLIC OF SLOVENIA
Slovenčeva ulica 22
1000 Ljubljana, Slovenia
www.jazmp.si info@jazmp.si
T +386 (0) 8 2000 500 F +386 (0) 8 2000 510

Številka: 312-20/2022-8
Datum: 28. 2. 2022

CERTIFIKAT O PROSTI PRODAJI
CERTIFICATE OF FREE SALE

S tem certifikatom Javna agencija Republike Slovenije za zdravila in medicinske pripomočke, Slovenčeva ulica 22, 1000 Ljubljana, Slovenija potrjuje, da ima pooblaščeni predstavnik proizvajalca registriran kraj poslovanja v Republiki Sloveniji, in da se lahko spodaj naveden pripomoček ali pripomočki v skladu z Uredbo o medicinskih pripomočkih (EU) številka 2017/745 tržijo na področju Unije.

V skladu z tretjim odstavkom 120. člena Uredbe o medicinskih pripomočkih (EU) 2017/745 se z odstopanjem od petega člena navedene Uredbe pripomoček, ki je pripomoček razreda I na podlagi Direktive 93/42/EGS, za katerega je bila izjava o skladnosti pripravljena pred 26.5.2021 in za katerega mora biti v postopek ugotavljanja skladnosti na podlagi te uredbe vključen priglašeni organ, ali, ki ima certifikat, ki je bil izdan v skladu z Direktivo 90/385/EGS ali Direktivo 93/42/EGS in, ki je veljaven na podlagi drugega odstavka 120. člena Uredbe o medicinskih pripomočkih (EU) 2017/745, lahko da na trg ali v uporabo do 26.5.2024, če je od 26.5.2021 še naprej skladen s katero koli od navedenih direktiv in če se zasnova in predvideni namen nista bistveno spremenila.

The Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Slovenčeva ulica 22, 1000 Ljubljana, Slovenia, hereby certifies, that the authorised representative has its registered place of business in the Republic of Slovenia and that the below-stated device or devices in compliance with the Regulation on medical devices (EU) 2017/745 may be marketed in the Union.

In compliance with the paragraph 3 of Article 120 of the Regulation on medical devices (EU) 2017/745 by way of derogation from Article 5 of the said Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of Articl 120e, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose.

Številka vloge vpisa medicinskega pripomočka / *Medical device registration application number*: 310-140/2021
Ime ali trgovsko ime pripomočka / *Name or trade name of the medical device*: Kirurški sukanec / *Surgical sutures*

Proizvajalca:
Manufacturer:

AKO MED d.o.o., Zdravka Čelara 12, 11000 Beograd, Republika Srbija
(podatki o proizvajalcu / *identification of the manufacturer)*

Pooblaščeni predstavnik proizvajalca:
Authorised representative:

BLACKSTONE, trgovina, proizvodnja ter podjetniško in poslovno svetovanje, d.o.o., Prešernova ulica 3, 2000 Maribor, Slovenija
(podatki o pooblaščenem predstavniku proizvajalca / *identification of the authorised representative)*

Ta certifikat je veljaven do izteka veljavnosti certifikata EU priglašenega organa z edinstveno identifikacijsko številko: / *This certificate is valid until the certificate EU of notified body with unique identifying number:*
5. 12. 2023, 2195-MED-1834001 (2195-MED-1834001-D01 and 2195-MED-1834001-D02) .

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOČKE
9
REPUBLIKA SLOVENIJA

Momir Radulović
Direktor / *Director*

Seznam medicinskih pripomočkov

List of Medical devices

	Generično ime **Generic Name**	**Razvrstitev** **Classification**	**Trgovsko ime** **Commercial Name**	**Model**
1	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON- Absorbable Surgical Sutures	JOST Polypropilen
2	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON- Absorbable Surgical Sutures	JOST Polyester
3	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON- Absorbable Surgical Sutures	JOST PVDF
4	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON- Absorbable Surgical Sutures	JOST PTFE
5	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON- Absorbable Surgical Sutures	JOST UHMWPE
6	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON- Absorbable Surgical Sutures	JOST ePTFE

	Generično ime Generic Name	Razvrstitev Classification	Trgovsko ime Commercial Name	Model
7	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON-Absorbable Surgical Sutures	JOST Polyamide
8	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST NON-Absorbable Surgical Sutures	JOST Silk
9	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST Absorbable Surgical Sutures	JOST PGA Quick
10	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST Absorbable Surgical Sutures	JOST PGLA Quick
11	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST Absorbable Surgical Sutures	JOST PGA
12	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST Absorbable Surgical Sutures	JOST PGLA
13	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST Absorbable Surgical Sutures	JOST PGCL
14	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST Absorbable Surgical Sutures	JOST PDO
15	Kirurški sukanec Surgical Sutures	Razred III Class III	JOST Absorbable Surgical Sutures	JOST PDO Barbed

Certified Translation from Serbian into English

Medicines and Medical Devices Agency of Serbia

Vojvode Stepe 458
11221 Belgrade
Republic of Serbia

E-mail: hygia@alims.gov.rs
www.alims.gov.rs

Registration no. 17616803
Taxpayer's ID no. 103605344
Giro account no. 840-712667-07

MEDICINES AND MEDICAL DEVICES AGENCY OF SERBIA (Logo)

No. 515-00-00472-2022-7-001
Date: 29 April 2022
Client:
AKO MED DOO BEOGRAD
Belgrade (Palilula), Zdravka Čelara 12

With regard to your application filed with the Medicines and Medical Devices Agency of Serbia under file no. 515-00-00472-2022-7 dated 25 March 2022 for a **Free Sale Certificate** in respect of the medical devices of the manufacturer: AKO MED d.o.o, Belgrade and pursuant to Article 3, paragraph 1, sub-paragraph 15) of the Law on Medical Devices (*Official Herald of the Republic of Serbia no. 105/2017*), the Medicines and Medical Devices Agency of Serbia hereby issues the following

FREE SALE CERTIFICATE

as evidence that the following medical devices made by the manufacturer: **AKO MED d.o.o., Belgrade** may be freely sold on the market in the Republic of Serbia and exported without restrictions:

Ord. no.	Medical Device Name	Generic name of the group of medical devices	Class	Decision no.	Decision issued on	Decision valid until
1.	JOST PDO	Surgical suture, absorbable, polydioxanone	III	515-02-00152-19-002	21/03/2019	03/02/2024
2.	JOST PGCL	Surgical suture, absorbable, polyglycolide caprolactone	III	515-02-00152-19-002	21/03/2019	03/02/2024
3,	JOST PGLA Quick	Surgical suture, absorbable, polyglycolide-L-lactide	III	515-02-00152-19-002	21/03/2019	03/02/2024
4.	JOST PGLA	Surgical suture, absorbable, polyglycolide-L-lactide	III	515-02-00152-19-002	21/03/2019	03/02/2024
5.	JOST PGA	Surgical suture, absorbable, polyglycolic acid	III	515-02-00152-19-002	21/03/2019	03/02/2024
6.	JOST PGA Quick	Surgical suture, absorbable, polyglycolic acid	III	515-02-00152-19-002	21/03/2019	03/02/2024
7.	JOST Polyester	Surgical suture, nonabsorbable, polyester	III	515-02-00987-19-002	14/05/2019	03/02/2024
8.	JOST UHMWPE	Surgical suture, nonabsorbable, polyethylene and polyester	III	515-02-00987-19-002	14/05/2019	03/02/2024
9.	JOST Polypropilen	Surgical suture, nonabsorbable, polypropylene	III	515-02-00987-19-002	14/05/2019	03/02/2024
10.	JOST PTFE	Surgical suture, nonabsorbable, polytetrafluoroethylene	III	515-02-00987-19-002	14/05/2019	03/02/2024

11.	JOST PVDF	Surgical suture, nonabsorbable, polyvinylidene fluoride	III	515-02-00987-19-002	14/05/2019	03/02/2024
12.	JOST Polyamide	Surgical suture, nonabsorbable, polyamide	III	515-02-02277-19-004	30/10/2019	03/02/2024
13.	JOST Silk	Surgical suture, nonabsorbable, silk	III	515-02-02277-19-004	30/10/2019	03/02/2024
14.	JOST PDO Barbed	Surgical suture, absorbable, polydioxanone, barbed	III	515-02-02166-20-003	13/08/2020	03/02/2024
15.	JOST ePTFE	Surgical suture, nonabsorbable, polytetrafluoroethylene	III	515-02-02168-20-003	06/07/2020	03/02/2024

(Concluded with ordinal no. 15)

In accordance with the Law on Medical Devices (*Official Herald of the Republic of Serbia no. 105/2017)* the Agency carries out entry of medical devices in the Register of Medical Devices and issues the relevant Decision on registration. The placement on the market and use of a medical device in the Republic of Serbia is conditional upon issuance of the Decision on the registration of a medical device in the Register of Medical Devices.

More specifically, the above medical devices of the following manufacturer: **AKO MED d.o.o. Belgrade** have been duly entered in the Register of Medical Devices by virtue of the relevant Decisions which serve as evidence that the above mentioned medical devices may be freely placed on the market in the Republic of Serbia and exported without any restrictions whatsoever.

Sincerely,

The Acting Director
Saša Jaćović, M.D. Specialist
(sgd.)

Round seal: Republic of Serbia
Medicines and Medical Devices Agency of Serbia - Belgrade

Агенција за лекове
и медицинска средства Србије
Војводе Степе 458
11221 Београд
Република Србија
e-mail: hygia@alims.gov.rs
www.alims.gov.rs
Матични број: 17616803
ПИБ: 103605344
Жиро рачун: 840-712667-07

Агенција за лекове и медицинска средства Србије

Број: 515-00-00472-2022-7-001
Датум: 29.04.2022
Клијент:
AKO MED DOO BEOGRAD
Beograd (Palilula), Zdravka Čelara 12

У вези вашег захтева заведеног у Агенцији за лекове и медицинска средства Србије под бр.515-00-00472-2022-7 од 25.03.2022. године, којим тражите **„Free Sale Certificate"** за медицинска средства произвођача „Ako Med d.o.o.", Београд, а на основу члана 3., став 1., тачка 15) Закона о медицинским средствима („Службени гласник РС", бр. 105/2017), Агенција за лекове и медицинска средства Србије издаје:

Free Sale Certificate

као потврду да се следећа медицинска средства **произвођача „Ako Med d.o.o.", Београд**, могу слободно наћи на тржишту у Републици Србији и да се несметано могу извозити:

R.b.	Naziv medicinskog sredstva	Grupa generičkih medicinskih sredstava	Klasa	Broj Rešenja	Datum izdavanja Rešenja	Datum važenja Rešenja
1.	JOST PDO	Hirurški konac, resorptivni, polidioksanon	III	515-02-00152-19-002	21/03/2019	03/02/2024
2.	JOST PGCL	Hirurški konac, resorptivni, poliglikolidkaprolakton	III	515-02-00152-19-002	21/03/2019	03/02/2024
3.	JOST PGLA Quick	Hirurški konac, resorptivni, poliglikolid-L-laktid	III	515-02-00152-19-002	21/03/2019	03/02/2024
4.	JOST PGLA	Hirurški konac, resorptivni, poliglikolid-L-laktid	III	515-02-00152-19-002	21/03/2019	03/02/2024
5.	JOST PGA	Hirurški konac, resorptivni, poliglikolna kiselina	III	515-02-00152-19-002	21/03/2019	03/02/2024
6.	JOST PGA Quick	Hirurški konac, resorptivni, poliglikolna kiselina	III	515-02-00152-19-002	21/03/2019	03/02/2024
7.	JOST Polyester	Hirurški konac, neresorptivni, poliestar	III	515-02-00987-19-002	14/05/2019	03/02/2024
8.	JOST UHMWPE	Hirurški konac, neresorptivni, polietilen i poliestar	III	515-02-00987-19-002	14/05/2019	03/02/2024
9.	JOST Polypropilen	Hirurški konac, neresorptivni, polipropilen	III	515-02-00987-19-002	14/05/2019	03/02/2024
10.	JOST PTFE	Hirurški konac, neresorptivni, politetrafluoroetilen	III	515-02-00987-19-002	14/05/2019	03/02/2024

11.	JOST PVDF	Hirurški konac, neresorptivni, polivinilidenfluorid	III	515-02-00987-19-002	14/05/2019	03/02/2024
12.	JOST Polyamide	Hirurški konac, neresorptivni, poliamid	III	515-02-02277-19-004	30/10/2019	03/02/2024
13.	JOST Silk	Hirurški konac, neresorptivni, svila	III	515-02-02277-19-004	30/10/2019	03/02/2024
14.	JOST PDO Barbed	Hirurški konac, resorptivni, polidioksanon	III	515-02-02166-20-003	13/08/2020	03/02/2024
15.	JOST ePTFE	Hirurški konac, neresorptivni, politetrafluoroetilen	III	515-02-02168-20-003	06/07/2020	03/02/2024

(Закључно са редним бројем 15.)

На основу Закона о медицинским средствима („Службени гласник РС“, бр. 105/2017), Агенција врши регистрацију медицинских средстава у Регистар медицинских средстава и о томе издаје Решење. Услов да се медицинско средство нађе на тржишту и у употреби у Републици Србији је да поседује Решење о регистрацији медицинског средства у Регистар медицинских средстава.

Конкретно, наведена медицинска средства **произвођача „Ako Med d.o.o.“, Београд**, су одговарајућим решењима регистрована у Регистар медицинских средстава. Ова решења представљају потврду да се наведена медицинска средства могу наћи на тржишту у Републици Србији и да се несметано могу извозити.

С поштовањем,

в.д. директора

Спец. др. мед. Саша Јаћовић