



СЕРТИФИКАТ

Настоящим удостоверяется, что система менеджмента качества

ООО "FAZO-LUXE"

ул. Оханграбо, 21, Ташкентский р-н, ССГ Гулистан, Ташкентская обл.,
111103, Республика Узбекистан

была проверена и признана соответствующей требованиям стандарта

ISO 13485:2016

в отношении разработки, производства и реализации медицинских изделий: бахил одноразовых полиэтиленовых, бинтов марлевых медицинских нестерильных и стерильных, бинтов тканых медицинских нестерильных, ваты медицинской гигроскопической нестерильной, марли медицинской отбеленной и масок лицевых гигиенических одноразовых из нетканого полотна

№: 20.1473.026

от 12 октября 2020 г.

Система менеджмента сертифицирована с 2017 года

Сертификат действителен до **5 мая 2023 г.**


Генеральный директор Ассоциации
по сертификации "Русский Регистр"

Уточнение области сертификации приведено в Приложении. Сертификат теряет силу в случае невыполнения условий сертификации (<http://www.rusregister.ru/doc/004.00-105.pdf>). Сертификат является собственностью Ассоциации по сертификации "Русский Регистр".





CERTIFICATE

This is to certify that the Quality Management System of

"FAZO-LUXE" LLC

21, Okhangrabo Str., Tashkent District, 111103, Gulistan community,
Tashkent region, Republic of Uzbekistan

has been assessed and found to be in accordance
with the requirements of

ISO 13485:2016

in respect of development, production and sales of medical devices:
polyethylene single-use shoe covers, sterile and non-sterile medical gauze
bandages, non-sterile medical woven bandages, non-sterile medical absorbent
cotton wool, bleached medical gauze and masks of facial hygienic
disposable from nonwoven fabric

No: 20.1473.026
of 12th October, 2020

Management system certified since 2017

This certificate is valid until **5th May, 2023**


Director General of Certification
Association "Russian Register"

Specification of the certification scope is provided in Annex. This certificate becomes invalid if conditions of certification are not fulfilled (<http://www.rusregister.ru/doc/004.00-105.pdf>). This Certificate is the property of Certification Association "Russian Register".



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM



Приложение к Сертификату
№ 20.1473.026
от 12 октября 2020 г.
бланк № 10-000219

**Область сертификации системы менеджмента
ООО "FAZO-LUXE"**

1. Продукция / услуги: разработка, производство и реализация медицинских изделий: бахил одноразовых полиэтиленовых, бинтов марлевых медицинских нестерильных и стерильных, бинтов тканых медицинских нестерильных, ваты медицинской гигроскопической нестерильной, марли медицинской отбеленной и масок лицевых гигиенических одноразовых из нетканого полотна.
2. Процессы выпуска продукции в соответствии с ISO 13485:2016:
 - 7.1. Планирование выпуска продукции
 - 7.2. Процессы, связанные с потребителем
 - 7.3. Проектирование и разработка
 - 7.4. Закупки
 - 7.5. Производство продукции и предоставление услуг
 - 7.6. Управление оборудованием для мониторинга и измерений
3. Исключения из процессов жизненного цикла продукции: 7.5.1f (в части действий после поставки), 7.5.3, 7.5.4, 7.5.9.2, 7.5.10, 8.4f

Генеральный директор Ассоциации
по сертификации "Русский Регистр"



А.В. Владимирцев

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate
№ 20.1473.026
of 12th October, 2020
registration form № 10-000220

Certification scope of management system of
"FAZO-LUXE" LLC

1. Product / service: development, production and sales of medical devices: polyethylene single-use shoe covers, sterile and non-sterile medical gauze bandages, non-sterile medical woven bandages, non-sterile medical absorbent cotton wool, bleached medical gauze and masks of facial hygienic disposable from nonwoven fabric.
2. Processes of product realization in compliance with ISO 13485:2016:
 - 7.1. Planning of product realization
 - 7.2. Customer-related processes
 - 7.3. Design and development
 - 7.4. Purchasing
 - 7.5. Production and service provision
 - 7.6. Control of monitoring and measuring equipment
3. Exclusions from the processes of product realization: 7.5.1f (regarding post-delivery activities), 7.5.3, 7.5.4, 7.5.9.2, 7.5.10, 8.4f.

Director General of Certification
Association "Russian Register"



A. Vladimirtsev



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Certification Association "Russian Register" has issued an IQNet recognized certificate that the organization:

"FAZO-LUXE" LLC

*21, Okhangrabo Str., Tashkent District, 111103, Gulistan community,
Tashkent region, Republic of Uzbekistan*

has implemented and maintains a

Quality Management System

for the following scope:

development, production and sales of medical devices: polyethylene single-use shoe covers, sterile and non-sterile medical gauze bandages, non-sterile medical woven bandages, non-sterile medical absorbent cotton wool, bleached medical gauze and masks of facial hygienic disposable from nonwoven fabric

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: 12th October, 2020

Expires on: 5th May, 2023

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: RU-20.1473.026




Alex Stoichitoui
President of IQNet


Arkady Vladimirtsev
*Director General of
Russian Register*



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



ANNEX 1 to IQNet Certificate
Number RU-20.1473.026

Certification scope of management system of
"FAZO-LUXE" LLC

1. Product / service: development, production and sales of medical devices: polyethylene single-use shoe covers, sterile and non-sterile medical gauze bandages, non-sterile medical woven bandages, non-sterile medical absorbent cotton wool, bleached medical gauze and masks of facial hygienic disposable from nonwoven fabric.
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 - 7.6. Control of monitoring and measuring equipment
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Alex Stoichitoiu
President of IQNet


Arkady Vladimirtsev,
Director General of
Russian Register



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NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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