



# СЕРТИФИКАТ

Настоящим удостоверяется, что система менеджмента качества

Общества с ограниченной ответственностью  
"Хлопчатобумажная компания "Навтекс"  
ул. Промышленная, 1, Наволоки, Ивановская область, 155830, Россия

была проверена и признана соответствующей требованиям стандарта

**ISO 13485:2016**

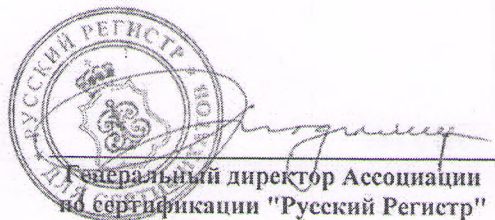
в отношении разработки, производства и продажи медицинских изделий: марля медицинская хлопчатобумажная отбеленная по ГОСТ 9412; марля медицинская хлопчатобумажная отбеленная по ТУ 9393-001-10715071-2014; бинты марлевые медицинские стерильные и нестерильные по ГОСТ 1172-93; салфетки марлевые медицинские стерильные по ГОСТ 16427-93; отрезы марлевые медицинские нестерильные по ТУ 9393-002-10715071-2014; бинты марлевые медицинские стерильные по ТУ 9393-004-10715071-2014; бинты марлевые медицинские нестерильные по ТУ 9393-005-10715071-2014; салфетки марлевые медицинские стерильные по ТУ 9393-006-10715071-2014; салфетки марлевые медицинские нестерильные по ТУ 9393-007-10715071-2014

№: 18.1998.026

от 31 октября 2018 г.

Система менеджмента сертифицирована с 2015 года

Сертификат действителен до 17 декабря 2021 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".

РУССКИЙ РЕГИСТР  
RUSSIAN REGISTER

10-000129





# CERTIFICATE

This is to certify that the Quality Management System of

**"Navtex Cotton Company", Ltd.**  
1, Promyshlennaya Str., 155830, Navoloki, Ivanovo region, Russia

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

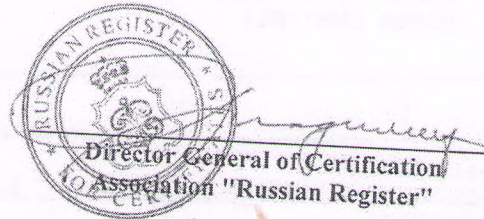
**ISO 13485:2016**

in respect of development, manufacture and sales of medical products:  
medical bleached cotton gauze according to GOST 9412;  
medical bleached cotton gauze according to TS 9393-001-10715071-2014;  
sterile and nonsterile medical gauze bandages according to GOST 1172-93;  
sterile medical gauze pads according to GOST 16427-93;  
medical nonsterile gauze cuts according to TS 9393-002-10715071-2014;  
sterile medical gauze bandages according to TS 9393-004-10715071-2014;  
nonsterile medical gauze bandages according to TS 9393-005-10715071-2014;  
sterile medical gauze pads according to TS 9393-006-10715071-2014;  
nonsterile medical gauze pads according to TS 9393-007-10715071-2014

No: 18.1998.026  
of 31<sup>st</sup> October, 2018

Management system certified since 2015

This certificate is valid until 17<sup>th</sup> December, 2021



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".

10-000130



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА  
RUSSIAN REGISTER CERTIFICATION SYSTEM



Приложение к Сертификату  
№ 18.1998.026  
от 31 октября 2018 г.  
бланк № 10-000129

**Область сертификации системы менеджмента  
Общества с ограниченной ответственностью  
"Хлопчатобумажная компания "Навтекс"**

1. Продукция / услуги: разработка, производство и продажа медицинских изделий: марля медицинская хлопчатобумажная отбеленная по ГОСТ 9412; марля медицинская хлопчатобумажная отбеленная по ТУ 9393-001-10715071-2014; бинты марлевые медицинские стерильные и нестерильные по ГОСТ 1172-93; салфетки марлевые медицинские стерильные по ГОСТ 16427-93; отрезки марлевые медицинские нестерильные по ТУ 9393-002-10715071-2014; бинты марлевые медицинские стерильные по ТУ 9393-004-10715071-2014; бинты марлевые медицинские нестерильные по ТУ 9393-005-10715071-2014; салфетки марлевые медицинские стерильные по ТУ 9393-006-10715071-2014; салфетки марлевые медицинские нестерильные по ТУ 9393-007-10715071-2014.
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. Обеспечение производства продукции и обслуживания
  - 7.6. Управление приборами для мониторинга и измерений
3. Исключения из процессов жизненного цикла продукции: 7.5.1 f) (в части действий после поставки), 7.5.3, 7.5.4, 7.5.6 (в части компьютерного программного обеспечения), 7.5.9.2

Генеральный директор Ассоциации  
по сертификации "Русский Регистр"



*А.В. Владимирцев*  
А.В. Владимирцев

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА  
RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate  
№ 18.1998.026  
of 31<sup>st</sup> October, 2018  
registration form № 10-000130

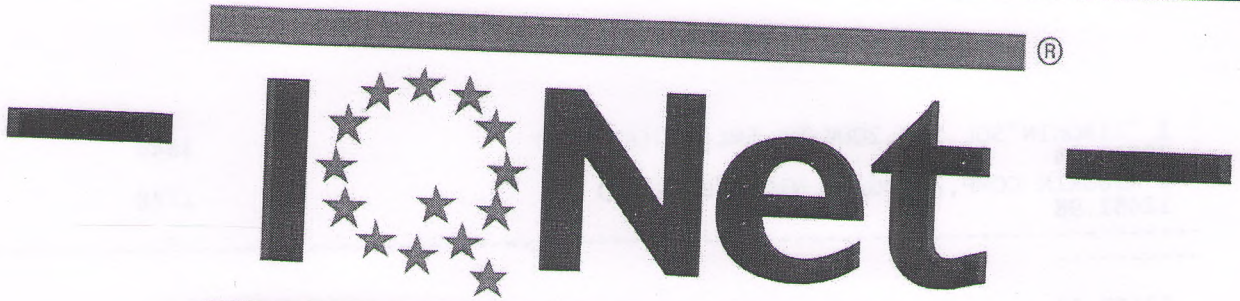
**Certification scope of management system of  
"Navtex Cotton Company", Ltd.**

1. Product / service: development, manufacture and sales of medical products: medical bleached cotton gauze according to GOST 9412; medical bleached cotton gauze according to TS 9393-001-10715071-2014; sterile and nonsterile medical gauze bandages according to GOST 1172-93; sterile medical gauze pads according to GOST 16427-93; medical nonsterile gauze cuts according to TS 9393-002-10715071-2014; sterile medical gauze bandages according to TS 9393-004-10715071-2014; nonsterile medical gauze bandages according to TS 9393-005-10715071-2014; sterile medical gauze pads according to TS 9393-006-10715071-2014; nonsterile medical gauze pads according to TS 9393-007-10715071-2014.
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 devices
3. Exclusions from the processes of product realization: 7.5.1 f) (with regard to actions after delivery), 7.5.3, 7.5.4, 7.5.6 (with regard to software applications), 7.5.9.2

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:

**"Navtex Cotton Company", Ltd.**

1, Promyshlennaya Str., 155830, Navoloki, Ivanovo region, Russia

has implemented and maintains a

**Quality Management System**

for the following scope:

development, manufacture and sales of medical products: medical bleached cotton gauze according to GOST 9412; medical bleached cotton gauze according to TS 9393-001-10715071-2014; sterile and nonsterile medical gauze bandages according to GOST 1172-93; sterile medical gauze pads according to GOST 16427-93; medical nonsterile gauze cuts according to TS 9393-002-10715071-2014; sterile medical gauze bandages according to TS 9393-004-10715071-2014; nonsterile medical gauze bandages according to TS 9393-005-10715071-2014; sterile medical gauze pads according to TS 9393-006-10715071-2014; nonsterile medical gauze pads according to TS 9393-007-10715071-2014

which fulfils the requirements of the following standard:

## ISO 13485:2016

Issued on: **31<sup>st</sup> October, 2018**  
Expires on: **17<sup>th</sup> December, 2021**

Registration Number: **RU-18.1998.026**



Alex Stoichitoiu  
President of IQNet

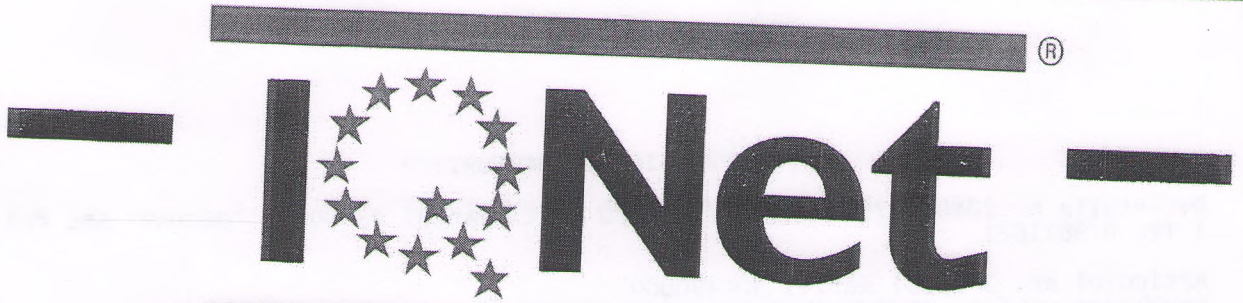
Arkady Vladimirtsev,  
Director General of  
Russian Register



**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 FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi 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  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



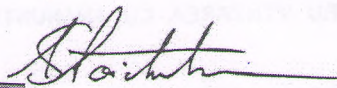
THE INTERNATIONAL CERTIFICATION NETWORK


**ANNEX 1 to IQNet Certificate**  
**Number RU-18.1998.026**

**Certification scope of management system of**  
**"Navtex Cotton Company", Ltd.**

1. Product / service: development, manufacture and sales of medical products: medical bleached cotton gauze according to GOST 9412; medical bleached cotton gauze according to TS 9393-001-10715071-2014; sterile and nonsterile medical gauze bandages according to GOST 1172-93; sterile medical gauze pads according to GOST 16427-93; medical nonsterile gauze cuts according to TS 9393-002-10715071-2014; sterile medical gauze bandages according to TS 9393-004-10715071-2014; nonsterile medical gauze bandages according to TS 9393-005-10715071-2014; sterile medical gauze pads according to TS 9393-006-10715071-2014; nonsterile medical gauze pads according to TS 9393-007-10715071-2014.
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 devices
3. Exclusions from the processes of product realization: 7.5.1 f) (with regard to actions after delivery), 7.5.3, 7.5.4, 7.5.6 (with regard to software applications), 7.5.9.2



  
Alex Stoichitoiu  
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 FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE Mexico 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  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)