

# 375055

# CERTIFICATE

No. 3750055



This is to certify that the Quality Management System of Medical Devices of

Trade and Production Private Unitary Enterprise **"FIATOS"**  
26, Fabrichnaya str., part of isolated premises 4N  
220033 Minsk  
Republic of Belarus

**Production site:**

11B-1, Smolenskaya str., Vitebsk, 210029, Republic of Belarus

has been assessed and found to be in compliance with the standard

**EN ISO 13485:2016**

applicable to

**Manufacturing of sterile surgical sutures with needle and without needle single use and manufacturing surgical meshes with and without accessories**



The certificate has been issued under No. **3750055** for the registration period from 25<sup>th</sup> March 2019 to 24<sup>th</sup> March 2022. The first certificate date of issue is 25<sup>th</sup> March 2019.

  
Approved by

  
Printed by



validity code: **9374C766-909**  
Check the validity of this certificate using this code at [www.ll-c.info](http://www.ll-c.info)

UE «FIATOS»	1. EC DECLARATION OF CONFORMITY	SMK 008.01
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### EC DECLARATION OF CONFORMITY

Manufacturer Address	TRADE-PRODUCTION PRIVATE UNITARY ENTERPRISE «FIATOS» 26, FABRICHNAYA STR., OF 18B (4N), MINSK, 220033, REPUBLIC OF BELARUS tel/fax: +375172210290, e-mail: fiatos@mail.ru
Manufacturing facilities Address	11b, Smolenskaya str. Vitebsk ,210029 Republic of Belarus; (BY - BELARUS) tel. +3752212481550 e-mail: fiatos@mail.ru
European Representative Address	ACTIVE EXPORT LTD 2nd Floor, 13 John Prince's Street, London ,United Kingdom Fax: +44 20 768 13 185 e-mail: active.expsu@gmail.com

Product name : Surgical sutures with needle and without needle sterile  
(see the annex to the EC declaration )

Classification	Class III, Medical device, Sterile
Cert.	9124.FITS
IQNet Certificate Number	109050
Scope of certification in language:	Manufacturing of sterile surgical sutures with needle and without needle single use and manufacturing surgical meshes with and without accessories
Standard	EN ISO 13485:2012
Applicable Additional Standards	EN 556-1:2011, ISO 11135, ISO 10993-7, ISO 11737-1, ISO 11607, ISO 14971
Partner / Certification Body	CISQ ( Italy)
Main Activity field EA/IAF	NA

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC and Commission Directive 2007/47/EC according to Annex II ,section 4 is required for medical devices. All supporting documentation is retained under the premise of the manufacturer .

Name

F.KLYHIN

Position  
Signature

General Manager

Effective Date :

2018-10-22

Date :

2018-10-22



Annex to the EC declaration of conformity

Manufacture : 210029 VITEBSK (BY - BELARUS)

Products : Surgical sutures with needle and without needle sterile

non-absorbable

- Suture , Polyvinylidene Fluoride (PVDF) monofilament
- Suture , Polypropylene monofilament
- Suture , Polyester braided
- Suture, Silk
- Suture, Kapron braided
- Suture, Kapron twisted
- Suture, Lavsan
- Suture, Polikaproamidny
- Suture , Silk virgin
- Suture, Ftoreks
- Suture, Nylon monofilament
- Suture, Nylon braided
- Suture , Polyester monofilament
- Suture, Filen
- Suture, Fiber Plus
- Suture, Polyphy I with and without Pledget
- Suture, Stainless steel monofilament
- Suture, tape Polyester
- Suture, Monoflon

absorbable

- Suture, PGA
- Suture, PGA Quick
- Suture, Lacryl
- Suture, Lacryl Quick
- Suture, PDS
- Suture, PGA MO
- Suture, Policril
- Suture, Monosorb

Name

Position  
Signature  
Date :



F.KLYHIN

General Manager

2018-10-22

