CERTIFICATE

No. 3750055

LL-C Certification

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

Digitally signed by Iarovoi Petru
Date: 2019.11.19 17:13:34 EET
Reason: MoldSign Signature
Location: Moldova

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

FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. • REPUBLICA MOLDOVA, mun. CHIŞINAU • IDNO 1004600013854 Sogno® S.R.L.

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

Approved by

Printed by

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

S 3137

SAFETY · ENVIRONMENT · QUALITY LL-C Certification

validity code: **9374C766-909**
Check the validity of this certificate using this code at **www.ll-c.info**

LL-C (Certification) Czech Republic a.s. | Pobřežní 620/3, 186 00 Praha 8

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 General Manager

Signature

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 F.KLYHIN

Position General Manager
Signature
Date : 2018-10-22