SZUTEST

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-391433301

Manufacturer: **APTOS LLC.**
Orbeliani Street 20/4, 0105 Tbilisi, GEORGIA

Product(s): **1. Sterile, Single Use Absorbable Surgical Sutures (with Needle/Cannula)**
2. Sterile, Single Use Non-Absorbable Surgical Sutures and Instruments

Model(s): Specification of products is given on the following page(s).

Reference Report No: MM0049-P005-R01, MM0049-P005-R02, MM0049-P007-R01

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 2024-05-26.

Issue Date: 2014-11-29
Revision No.: 03 Rev.
Revision Date: 2021-04-16

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. 1/2_2195-MED-391433301 Rev.03

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

SZUTEST

Certificate Number: 2195-MED-391433301

Product Models:

1. Sterile, Single Use Absorbable Surgical Sutures (with Needle/Cannula)	
P(LA/CL) [Poly(L-lactide-co-ε-caprolactone)]	With Barbs
	Spirally Wrapped Around the Needle/Cannula, without Barbs
	Twisted Pair Threads, without Barbs
	Intimate Excellence Method HA
	Intimate Excellence Method

2. Sterile, Single Use Non-Absorbable Surgical Sutures and Instruments	
PP (Polypropylene)	With Barbs
	Spirally Wrapped Around the Needle/Cannula, without Barbs
	Curved Needle
Instruments	Stainless Steel Multifilament
	Millennium Cannula - Transparent PET Tube

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

SZUTEST

EC DESIGN EXAMINATION CERTIFICATE

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

Certificate Number: 2195-MED-391433301-D01

Manufacturer:	**APTOS LLC.** Orbeliani Street 20/4, 0105 Tbilisi, GEORGIA
Product(s):	**Sterile, Single Use Absorbable Surgical Sutures (with Needle/Cannula)**
Model(s):	**P(LA/CL) [Poly(L-lactide-co-ε-caprolactone)]** 1. With Barbs 2. Spirally Wrapped Around the Needle/Cannula, without Barbs 3. Twisted Pair Threads, without Barbs 4. Intimate Excellence Method HA 5. Intimate Excellence Method
Reference Report No:	MM0049-P005-R01, MM0049-P005-R02, MM0049-P007-R01

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 2024-05-26.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Rukiye BALKAN
Deputy General Manager

Issue Date:	2014-11-29
Revision No.:	02 Rev.
Revision Date:	2021-04-16

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

SZUTEST

CERTIFICATE INFO AMENDMENT

SERTİFİKA BİLGİ DEĞİŞİKLİĞİ

According to Article 120(3) of the Regulation (EU) 2017/745 on Medical Devices

(AB) 2017/745 Tıbbi Cihazlar Yönetmeliği Madde 120(3)'ye göre

Effected Certificate Number(s): *Etkilenen Sertifika Numarası(ları):*	**2195-MED-391433301, 2195-MED-391433301-D01**
Manufacturer: *Üretici*	**APTOS LLC.** Givi Amilakhvari Street 15, 0109 Tbilisi, GEORGIA
Product(s): *Ürün(ler)*	No change
Model(s): *Model(ler)*	No change
Reference Report No: *Referans Rapor No*	MM0049-P008-R01, MM0049-P008-R02, MM0049-P008-R03
Definition of the Change: *Değişikliğin Tanımı*	Change of manufacturing site and head office

SZUTEST, Notified Body 2195, declares and the above mentioned manufacturer has initiated an insignificant change according to Article 120(3) of (EU) 2017/745 and MDCG 2020-3 guidance and therefore the information on the effected 93/42/EEC certificate(s) has been changed as described above.

This document is a confirmation for authorities and cannot be used as other purposes.

2195 kimlik numaralı Onaylanmış Kuruluş SZUTEST, yukarıda belirtilen üreticinin (AB) 2017/745 Regülasyonu Madde 120(3)'e ve MDCG 2020-3 rehber dokümanına göre önemli olmayan bir değişiklik yürüttüğünü ve bu sebeple etkilenen 93/42/AT sertifika(lar)ındaki bilgilerin yukarıdaki gibi değiştiğini beyan eder.

Bu doküman yetkili otoriteler için bir onay niteliğinde olup farklı bir amaçla kullanılamaz.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date/*Yayın Tarihi:* 2021-11-04

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı