



# C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2018.106.10375-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Katsan Katgüt San. ve Tic. A.Ş.

Company Address : AOSB 10041 Sokak No:22 Çiğli, İZMİR / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II  
(Excluding Section 4)

Product : ALCASORB® (Sterile absorbable PGA suture) With/Without needle - Class III  
ALCASORB® RAPID (Sterile absorbable PGA RAPID suture)  
With/Without needle - Class III  
ALCALACTINE® (Sterile absorbable PGLA suture) With/Without needle - Class III  
ALCALACTINE® RAPID (Sterile absorbable PGLA RAPID suture)  
With/Without needle - Class III  
ALCALACTONE® (Sterile absorbable PGCL suture) With/Without needle - Class III  
ALCADINONE® (Sterile absorbable PDO suture) With/Without needle - Class III  
ALCALENE® (Sterile non-absorbable Polypropylene (PP) suture)  
With/Without needle - Class IIb  
ALCASILK® (Sterile non-absorbable Silk suture) With/Without needle - Class IIb  
ALCAMIDE® (Sterile non-absorbable PA suture) With/Without needle - Class IIb

GMDN : 13908, 17471, 45814, 13909, 13910, 16584, 38000

Product Types are attached.

Certificate Number : M.2018.106.10375

Report Number : MD.3589.IB

Initial Assessment Date : 04.05.2018

Registration Date : 10.09.2018

Revision Date /No : 12.07.2019/03

Expiry Date : 09.09.2023

  
UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)



This document containing 3 (three) pages is the Annex of the Certificate with the revision number 03, with the number M.2018.106.10375 and with the registration date of 10.09.2018 with the revision date of 12.07.2019 issued for "Katsan Katgüt San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

<b>ALCASORB Polyglycolic acid (PGA)</b>
<b>GMDN NO:13908</b>
Synthetic, sterile (EtO), absorbable, multifilament, braided, coated, violet-colored surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
<b>USP:</b> 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3
<b>EP:</b> 0,7 1 1,5 2 3 3,5 4 5 6
<b>Suture Lengths :</b> Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths :</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes :</b> 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties:</b> Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula

<b>ALCASORB RAPID Polyglycolic acid degraded (PGA)</b>
<b>GMDN NO:13908</b>
Synthetic, sterile (R), absorbable, multifilament, braided, coated, beige-colored (undyed) surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
<b>USP:</b> 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
<b>EP:</b> 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths :</b> Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths :</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes :</b> 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties:</b> Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula

<b>ALCALACTINE Poly[glycolic acid (90%)-co-lactic acid (10%)] (PGLA)</b>
<b>GMDN NO:17471</b>
Synthetic, sterile (EtO), absorbable, multifilament, braided, coated, violet-colored surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
<b>USP:</b> 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
<b>EP:</b> 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths :</b> Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths :</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes :</b> 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties:</b> Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula

<b>ALCALACTINE RAPID Poly[glycolic acid (90%)-co-lactic acid (10%)] degraded (PGLA)</b>
<b>GMDN NO:17471</b>
Synthetic, sterile (R), absorbable, multifilament, braided, coated, beige-colored (undyed) surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
<b>USP:</b> 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
<b>EP:</b> 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths :</b> Variety of lengths, from 10 cm to 150 cm



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<b>Needle Lengths</b> : Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes</b> : 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties</b> : Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula

  

<b>ALCALACTONE Poly[glycolic acid (75%)-co-caprolactone (25%)] (PGCL)</b>
<b>GMDN NO:45814</b>
Synthetic, sterile (EtO), absorbable, monofilament, violet-colored surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
USP: 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths</b> : Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths</b> : Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes</b> : 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties</b> : Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula

  

<b>ALCADINONE Polydioxanone</b>
<b>GMDN NO:16584</b>
Synthetic, sterile (EtO), absorbable, monofilament, violet-colored surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
USP: 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths</b> : Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths</b> : Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes</b> : 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties</b> : Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula

  

<b>ALCALENE Polypropylene (PP)</b>
<b>GMDN NO:13909</b>
Synthetic, sterile (EtO), non-absorbable, monofilament, blue-colored surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
USP: 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
EP: 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths</b> : Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths</b> : Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes</b> : 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties</b> : Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula



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<b>ALCASILK Silk</b>
<b>GMDN NO:13910</b>
Natural, sterile (EtO), non-absorbable, multifilament, braided, coated, black-colored surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
<b>USP:</b> 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
<b>EP:</b> 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths :</b> Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths :</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes :</b> 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties:</b> Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula
<b>ALCAMIDE Polyamide</b>
<b>GMDN NO:38000</b>
Synthetic, sterile (EtO), non-absorbable, monofilament, blue-colored surgical sutures are loop, single or with double needle or without needle, and in the following USP, EP, suture length, needle length, needle shape and needle properties:
<b>USP:</b> 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2
<b>EP:</b> 0,7 1 1,5 2 3 3,5 4 5
<b>Suture Lengths :</b> Variety of lengths, from 10 cm to 150 cm
<b>Needle Lengths :</b> Variety of lengths, from 3 mm to 150 mm
<b>Needle Shapes :</b> 1/2, 3/8, 1/4, 5/8, Straight, J
<b>Needle Properties:</b> Round Body, Round Body Heavy, Taper Point, Taper Point Heavy, Blunt Point, Blunt Point Heavy, Cutting, Cutting Premium, Reverse Cutting, Reverse Cutting Premium, Taper Cut, Taper Cut Heavy, Diamond, Spatula, Premium Spatula

