



# EC CERTIFICATE

## EC Design-Examination Certificate For Medical Devices

### MDD 93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2018.106.10375 the validity of the certificate  
M.2018.106.10375-1 will also end.

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

Company Address : 1571. Sokak No:22 Çınarlı, İZMİR / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive – Annex II  
(Including 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

GMDN : 13908, 17471, 45814

Product Types are attached.

Certificate Number : MM.2018.106.10375-1


Report Number : MD.3589.IB-1

Initial Assessment Date : 04.05.2018

Registration Date : 10.09.2018

Revision Date /No : -

Expiry Date : 09.09.2023

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

The EC desing examination certificate refers to the above mentioned product.It certifies that the desing documentation of the product complies with Annex II,article 4 of the directive. 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 man ufacturer 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 expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udem.com.tr.

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This document containing 2 (two) pages is the Annex of the Certificate with the number M.2018.106.10375-1 and with the registration date of 10.09.2018 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

**ALCASORB Polyglycolic acid (PGA)**

**GMDN NO:13908**

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:

**USP:** 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3

**EP:** 0,7 1 1,5 2 3 3,5 4 5 6

**Suture Lengths :** Variety of lengths, from 10 cm to 150 cm

**Needle Lengths :** Variety of lengths, from 3 mm to 150 mm

**Needle Shapes :** 1/2, 3/8, 1/4, 5/8, Straight, J

**Needle Properties:** 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

**ALCASORB RAPID Polyglycolic acid degraded (PGA)**

**GMDN NO:13908**

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:

**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

**Suture Lengths :** Variety of lengths, from 10 cm to 150 cm

**Needle Lengths :** Variety of lengths, from 3 mm to 150 mm

**Needle Shapes :** 1/2, 3/8, 1/4, 5/8, Straight, J

**Needle Properties:** 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

**ALCALACTINE Poly[glycolic acid (90%)-co-lactic acid (10%)] (PGLA)**

**GMDN NO:17471**

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:

**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



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<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><u>ALCALACTINE RAPID Poly[glycolic acid (90%)-co-lactic acid (10%)] degraded (PGLA)</u></b>
<b><u>GMDN NO:17471</u></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><u>ALCALACTONE Poly[glycolic acid (75%)-co-caprolactone (25%)] (PGCL)</u></b>
<b><u>GMDN NO:45814</u></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:
<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