



C E R T I F I C A T E

EC Design-Examination Certificate

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

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

GMDN : 13908, 17471, 45814, 16584

Product Types are attached.

Certificate Number : M.2018.106.10375-1

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.

The EC design examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, 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 aforementioned 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 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.

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This document containing 2 (two) pages is the Annex of the Certificate with the revision number 03, with the number M.2018.106.10375-1 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

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
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 RAPID Poly[glycolic acid (90%)-co-lactic acid (10%)] degraded (PGLA)
GMDN NO:17471
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



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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
ALCALACTONE Poly[glycolic acid (75%)-co-caprolactone (25%)] (PGCL)
GMDN NO:45814
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
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
ALCADINONE Polydioxanone
GMDN NO:16584
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
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