

This document containing 2 (two) pages is the Annex of the Certificate with the number M.2018.106.11727 and with the registration date of 10.04.2019 issued for "Shanxian HAIDIKE Biotechnology Co., Ltd." 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

[Polyglycolic acid] (PGA)

GMDN NO:13908

Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or 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: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6

EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7, 8

Suture Lengths: Variety of lengths, from 10 cm to 500 cm

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

Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI

Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

Poly[glycolide(90%)-co-lactide(10%)] (PGLA)

GMDN NO:17471

Synthetic, Sterile, Absorbable, Multifilament, Braided, Undyed or 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: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2

EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5

Suture Lengths: Variety of lengths, from 10 cm to 500 cm

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

Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI

Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

[Polyamide 6] (Nylon)

GMDN NO:13905

Synthetic, Sterile, Non-Absorbable, monofilament, 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: 11/0,10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4,

EP: 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6

Suture Lengths: Variety of lengths, from 10 cm to 500 cm

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

Needle Shapes: 1/2, 3/8, 1/4, 5/8, 4/9, Straight, J, SKI

Needle Properties: Round Body, Reverse Cutting, Reverse Cutting Premium, Reverse Cutting Premium Thin Line, Reverse Cutting Slim Blade, CC Needle, Cobra, Diamond, Sabre, Micro point, Straight Cutting, Lancet, Spatula, Taper cutting, Taper point Plus, Trocar Point, Taper Point, Inside Cutting, Inside Cutting Premium, Inside Cutting Premium Thin Line, Inside Cutting Slim Blade, Square Body, Blunt Point, Ball Point.

[Fibroin] (Silk)

GMDN NO:13910

Synthetic, Sterile, Non-Absorbable, Multifilament, Braided, 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: 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5

EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6, 7

Su ure Lengths: Variety of lengths, from 10 cm to 500 cm

UDEM International Certification
Auditing Training Certific Indiator BIAGNOST:
and Trade Inc. Co. 2

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Sayfa 1/2

BOND