

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CADDESİ 91A ORTAHİSAR - TRABZON - TÜRKİYE

**CERRAHİ İPLİKLER, GEÇİCİ PACE TELLERİ VE EMİLEBİLİR HEMOSTAT
TASARIMI, ÜRETİMİ VE SATIŞI**

kapsamında

EN ISO 13485:2016

Uluslararası Tıbbi Cihazlar Kalite Yönetim Sistemi Standardına uygun bir yönetim sistemi kurmuştur.

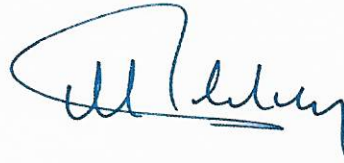
"Standardın aşağıda verilen maddeleri hariç tutulmuştur"
"7.5.3" "7.5.4"

Sertifika No : M 11652
İlk Belgelendirme Tarihi : 20 Şubat 2019
Sertifika Tarihi : 05 Ocak 2022
Son Geçerlilik Tarihi : 04 Ocak 2025

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No: 15 Tepeören Tuzla
İstanbul / Türkiye

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

Sertifikalar periyodik ara denetimlerin başarılı ile tamamlanması kaydıyla geçerlidir. Detaylı bilgi için yukarıdaki numaralara başvurulabilir.



Genel Müdür



DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CADDESİ 91A ORTAHİSAR - TRABZON - TURKEY

**DESIGN, PRODUCTION AND SALES OF SURGICAL SUTURES, TEMPORARY
PACING WIRES AND ABSORBABLE HEMOSTAT**

with a scope of

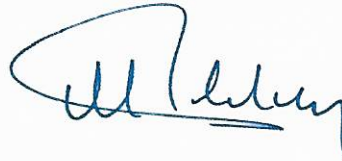
EN ISO 13485:2016**Has established a management system in accordance
with international Medical Devices Quality Management System Standard***"Following elements of the standard are excluded"**"7.5.3" "7.5.4"*

Certificate No	: M 11652
Initial Certification Date	: 20 February 2019
Certification Date	: 05 January 2022
Expiration Date	: 04 January 2025

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No. 15 Tepeören Tuzla
İstanbul / Turkey

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Certificate is valid till expiration date,
subject to successful completion of
periodical surveillance audits.
Please contact above numbers for
detailed information.



General Manager



TÜRKAK BDS NO
YS-6478-8BE3

EC Certificate
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-784

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CAD. 91A, ORTAHİSAR, TRABZON - TURKEY

Products: PEGELAK, PEGELAK rapid, PEGESORB, PEGESORB rapid, TROFİLEN, DAYLON, İPEK, PROPİLEN, POLİTER, TEKMON, PEDESENTE, TEKTEL, DOPACE, KANSTAT, DAXTON, ONTREX, xnat pedesente, xnat®tekmon

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.6104.01

Expiry Date: 27 May 2024



Muhteşem Gökhan Yücel
Head of Notified Body

17 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:**Page 1/3**

**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-21-784**

Concerned medical devices;

Product: PEGELAK®

Poly(glycolide-co-lactide) Absorbable Braided Surgical Suture

Types: With or without Needles, Violet or Undyed, Coated

Product: PEGELAK®rapid

Poly(glycolide-co-lactide) Absorbable Braided Surgical Suture

Types: With or Without Needles, Undyed, Coated

Product: PEGESORB®

Polyglycolic Acid Absorbable Braided Surgical Suture

Types: With or Without Needles, Violet or Undyed, Coated

Product: PEGESORB®rapid

Polyglycolic Acid Absorbable Braided Surgical Suture

Types: With or Without Needles, Undyed, Coated

Product: DAYLON®

Polyamide Non-Absorbable Monofilament Surgical Suture

Types: with single/double needle(s)

Product: TROFİLEN®

Polyvinylidene Fluoride Non-Absorbable Monofilament Surgical Suture

Types: with single/double or without needle(s)

Product: İPEK®

Silk Non-Absorbable Braided Surgical Suture

Types: With single/double or without needle(s)



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Certificate Number: 1984-MDD-21-784**

Concerned medical devices;

Product: PROPİLEN®

Polypropylene Non-Absorbable Monofilament Surgical Suture

Types: With or without needle(s), with or without PTFE Pledgets

Product: POLİTER®

Polyester Non-Absorbable Braided Surgical Suture

Types: With single/double or without needle(s), with or without PTFE Pledgets

Product: TEKMON®

absorbable monofilament surgical suture Poly(glycolide-co-caprolactone)

Types: Undyed or violet, with single/double or without needle(s)

Product: PEDESENTE®

absorbable monofilament surgical suture (Polydioxanone)

Types: Undyed or violet, with single/double or without needle(s)

Product: TEKTEL®

Surgical Stainless Steel Wire

Types: With fixed or Rotating Needle, Natural-Metallic, Noncoated/Nonsheated

Product: DOPACE®

Temporary Pacing Wire

Types: Twisted 316L stainless steel, insulated, with double needle, with or without anchor

Product: KANSTAT®

Absorbable Hemostat (Oxidized Regenerated Cellulose)

Types: KANSTAT® ORJ

KANSTAT® FABRIC

KANSTAT® FELT

KANSTAT® FIBRIL



Muhteşem Gökhan Yücel
Head of Notified Body

17 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

Enclosure of the EC Certificate:

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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-21-784**

Concerned medical devices;

Product: DAXTON®

DAXTON®- D (PTFE) and DAXTON®- K (ePTFE)

Non-Absorbable, monofilament surgical suture

Types: with single/double or without needle(s)

Product: ONTREX®

Polyethylene Non-absorbable Multifilament Surgical Suture and Tape

Types: With needles (single or double) or without needles

Product: xnat®pedesente

Knotless Tissue Control Device, Polydioxanone Absorbable Monofilament Barbed Suture

Types: uni-directional or bi-directional, spiral or non-spiral barbed type, with a fixation tab or end-loop design, in a variety of lengths, with or without needles, violet or undyed

Product: xnat®tekmon

Knotless Tissue Control Device, Poly (glycolide-co-caprolactone) Absorbable Monofilament Barbed Suture

Types: uni-directional or bi-directional, spiral or non-spiral barbed type, with a fixation tab or end-loop design, in a variety of lengths, with or without needles, violet or undyed

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel
Head of Notified Body

17 May 2021, Istanbul, Turkey

*Touching
the hearts for*
A HALF CENTURY



Surgical Sutures

Dopace®

Temporary Pacing Wire



TEMPORARY PACING WIRE, twisted 316L stainless steel wire, with polyethylene (PE) coated (sheathed) with double needle, with or without anchor.

DOPACE is indicated for use as temporary cardiac pacing wire to transfer electrical energy along its length between the external pacemaker and the patient's heart for temporary cardiac pacing and intracardial ECG monitoring during and after open-heart surgery, for single use only.

DOPACE, TPW are available as multifilament sheathed in metric 3.0 (USP 2/0) gauge size, in a variety of lengths (mostly 60 cm), with anchor or without, with permanently attached needles

Doğsan, TPW meets all requirements established by the recent EP and the USP for non-absorbable surgical sutures, except the coating and also can be defined with the Brown & Sharpe Gauge (B&S) or American Wire Gauge (AWG) classifications.

Product Code	Product Specifications
E5601W	Dopace 2/0 60 mm straight cutting (▼), breakaway needle, with anchor, 17 mm 1/2 round bodied, 60 cm
E5603W	Dopace 2/0 60 mm straight cutting (▼), breakaway needle, with anchor, 25 mm 1/2 round bodied, 60 cm
E5903W	Dopace 2/0 90 mm straight cutting (▼), breakaway needle, with anchor, 22 mm 3/8 round bodied, 60 cm
E5613W	Dopace 2/0 60 mm straight cutting (▼), breakaway needle, 25 mm 1/2 round bodied, 60 cm
E5913W	Dopace 2/0 90 mm straight cutting (▼), breakaway needle, 22 mm 3/8 round bodied, 60 cm
E5611W	Dopace 2/0 60 mm straight cutting (▼), breakaway needle, 17 mm 1/2 round bodied, 60 cm