EC DECLARATION OF CONFORMITY

We, APEX TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ SAN. TİC. LTD. ŞTİ.

herewith declare that the following described product meets the provisions of the following directives. All supporting documentation is retained under the premises of the manufacturer.

PRODUCT : DISPOSABLE FACE MASK

MODEL : TIE ON, EARLOOP

CLASS : CLASS 1

APPLICABLE EC DIRECTIVES :
93/42/EEC MEDICAL DEVICE DIRECTIVE

APPLICABLE STANDARDS :
TS EN 14683 SURGICAL MASK
TS EN 15223-1 LABEL SYMBOLS OF MEDICAL DEVICES
TS EN ISO 14971 APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
TS EN ISO 10993 series BIOCOMPATIBILITY

CONTACT INFORMATIONS :
H.Sabancı Org. San. Böl. Ordu Cad. No: 23
Yakapınar / ADANA / TURKEY
Phone : +90 322 3944470 (3 line) Fax : +90 322 3944473
e-mail : info@amet.com.tr Web : www.amet.com.tr

DATE OF ISSUE : 25.09.2016

SIGNATURE :

HİMMET ATİK
General Manager

Apex TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ SANAYİ TİCARET LİMİTED ŞİRKETİ
Hacı Sabancı Organize Sanayi Bölgesi
Ordu Cad. No: 23 Seyhan / ADANA
Tel: 0322 394 44 70 (PBX) Fax: 0322 394 44 73
Yüreğir V.D. 619 014 8335

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Türkiye

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Medizinische Einmalartikel und Absauggeräte
Disposable medical devices and devices for aspiration and vacuum extraction

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 04 232 980886
Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-16
bis / *until* 2023-09-16
Edition 8

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-16

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIb
Products of class IIb

Pressure Monitoring Set
Leukocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

Thoracenthesis Set
Thoracic Catheter
Arterial Needle
Endotracheal Tube
Reinforced Endotracheal Tube
RAE Endotracheal Tube
Nasogastric Catheter
Stomach Catheter
Feeding Catheter
Manifold / Manifold Pressure
Three-Way Stopcock

Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-20

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Tourniquet Set
IV Cannula
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannula
Oxygen Connecting Tube
Tracheostomy Tube
Extracorporeal PVC Tubing
Extracorporeal Tubing Set
Quick Prime Set
Cardioplegia Set
Wound Drainage Set
Infusion Pump Set
Yankauer Suction Set
Suction Connecting Tube
Surgical Braided Tape
Nelaton Catheter
Tiemann Catheter

Bericht Nr. / *Report No.* 3524 7139
3526 6208
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Gültigkeit / *Validity*
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Edition 15

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Hydrophilic coated uretheral Catheter
IV Filter Set
Aspirators
Blood Transfusion Set
Rectal Catheter
Umbilical Catheter
Angiographic Kit
B-Soft Kit
Aortic Punch
Gas Sampling Line
External Drainage Set
Vent Catheter
Vessel Cannula

Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
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Edition 15

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Essen, 2020-04-20

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

Urine Collection Bag
Pleural Drainage Set
Central Venous Pressure Set
Guedel Airway
Spigot
Extension Lines
Kapkon Connector
Straight Connector
Straight Luer Connector
Y Connector
Y Luer Connector
Stopper
Instopper
Umbilical Cord Clamp
T.U.R. Set / Arthroscopy set
Transfer Set
Intravenous Infusion Sets
Intravenous Infusion Sets / Flowmeter
Intravenous Infusion Sets / Burette

Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

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www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

B-Safe
Intubation Stylet
Combi Stopper
Urimeter
Thoracic Drainage Set
Vaginal Specula
ENEMA Set
I.V. Infusion Set w/B-Flow Flow Regulator
Control Syringe
Meconium Aspiration Connector

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Im (mit Messfunktion)
Products of class Im (with measuring function)

Urimeter
C.V.P. Set
Pleural Drainage Set
Volumetric Exerciser (B-Spiro)
Infusion Set w/Burette
Thoracic Drainage Set

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.
Note: *For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.*

Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

MINISTERUL SĂNĂTĂŢII, MUNCII ŞI PROTECŢIEI SOCIALE AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ, ТРУДА И СОЦИАЛЬНОЙ ЗАЩИТЫ РЕСПУБЛИКИ МОЛДОВА
AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, mun. Chişinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: ansp@ansp.md; anticamera@ansp.md

DOCUMENTAŢIE MEDICALĂ / Медицинская документация
FORMULAR / Форма **Nr. 303-2/e**
APROBAT DE MSMPS al RM / Утверждена МЗТСЗ РМ
31.10.11 Nr. 828

Centrul de încercări de laborator acreditat de către Centrul Naţional de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LI-044 din 17.02.2018 valabil până la 16.02.2022
Acreditat în Sistemul Ministerului Sănătăţii, Muncii şi Protecţiei Sociale al RM
Аккредитованный в системе Министерства Здравоохранения, Труда и Социальной Защиты Республики Молдова
Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR
PENTRU PRODUSELE ALIMENTARE ŞI NEALIMENTARE Nr. P - 8962/2021

Санитарное заключение для пищевых и непищевых продуктов

din/*от* " 17 " februarie a./*г.* **2021**

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Articole igienice - aparate de ras, spumă pentru ras m.c.DERBY

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / *указать полное наименование санитарного (ых) регламента (ов)*
Regulamentului sanitar privind produsele cosmetice aprobat prin HG nr. 1207 din 02.11.2016

Organizaţia-producătoare/importatoare, ţara de origine / *организация произв./импортер, страна происхождения*

Turcia, AZMUSEBAT CELIK SANAYI VE TICARET A.S.

Destinatarul avizului sanitar / *получатель санитарного заключения*

FPC "TEHELAN" SRL, Moldova, Chişinău, str.Doina, 199/1

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило
Demers, aviz sanitar nr.P-2679/2019 din 30.08.2019, contract din 01.06.2017, certificate calitate, declaraţie, invoice, raport a încercărilor de laborator nr.586-587 din februarie 2021
(a enumera documentele de însoţire, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*
Parametrii (factorii) / *показатели (факторы)* **Normativul sanitar /** *санитарный норматив*

conform rapoartelor încercărilor de laborator nr.586-587 din februarie 2021

Domeniu de utilizare / *Область применения:* întreţinere, igienă

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*
importul, plasarea pe piaţă în condiţiile respectării legislaţiei în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 28 februarie 2022

Int. **DIRECTORUL AGENŢIEI NAŢIONALE PENTRU SĂNĂTATE PUBLICĂ**

Vasile GUŞTIUC
(numele, prenumele/ Ф.И.О.)

(semnătura / подпись)

L.Ş.

SP 10-XVI-09

ANSP/HAO3

O3

CERTIFICATE

AT Sertifikası
Tasarım İnceleme
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 4

Sertifika Numarası: 1984-MDD-21-787

Aşağıda listesi verilen cihazların tasarım incelemesinin, Tıbbi Cihazlar Yönetmeliği 93/42/EEC Ek II Bölüm 4'e göre, konu oldukları ulusal yasaların gereksinimlerine uygun olarak tarafımızca gerçekleştirildiğini beyan ederiz. Aşağıda listesi verilen cihazların tasarımlarının Tıbbi Cihazlar Yönetmeliği 93/42/EEC Ek II Bölüm 4'ün ulusal yasalarda karşılığını bulan ilgili şartlarına uygun olduğunu onaylarız.

Kuruluş:

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CAD. 91A, ORTAHİSAR, TRABZON - TÜRKİYE

Ürün: DOPACE®

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir (1) sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Bu sertifika kapsamında olan sınıf III ürünler için ayrıca Tıbbi Cihaz Yönetmeliği Tam Kalite Güvence Sistemi 93/42/AT Ek-II Bölüm 3 sertifikası da zorunludur.

Rapor No: M.6104.01

Son Geçerlilik Tarihi: 27 Mayıs 2024

17 Mayıs 2021, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

AT Sertifikası Eki:

Tasarım İnceleme

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 4

Sertifika Numarası: 1984-MDD-21-787

İlgili tıbbi cihazlar;

Ürün: DOPACE®
Geçici Pace Teli
Tipleri: Bükülü 316L paslanmaz çelik, izolasyonlu Çift iğneli, çapalı veya çapasız, steril
Model Numarası:

İplik Anma No (Çap) EP/USP	*Pace Teli Uzunluğu (cm)*	*Kavisli İğne Uzunluğu*	*Kavisli İğne yayı*	*Kavisli İğne Çeşitleri*	*Kırılabilir İğne Uzunluğu*
USP 2/0	60 cm	17-25 mm	⅜ veya ½	Yuvarlak	60-90

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

17 Mayıs 2021, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

EC Certificate
Design Examination According to
Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-787

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

Organization

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CAD. 91A, ORTAHİSAR, TRABZON - TURKEY

Product: DOPACE®

The products defined at the enclosure which is the part of this certificate and contains one (1) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 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

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 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

CERTIFICATE

Enclosure of the EC Certificate:

Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-787

Concerned medical devices;

Product: DOPACE®
Temporary Pacing Wire
Types: Twisted 316L stainless steel, insulated, with double needle, with or without anchor
Model Number:

Diameter EP/USP range	*Pace Wire length(cm)*	*Curved Needle length*	*Curved Needle Curvature*	*Curved Needle type*	*Break away Needle length*
USP 2/0	60 cm	17-25 mm	⅜ or ½	Round	60-90

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

17 May 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 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

CERTIFICATE

AT Sertifikası
Tasarım İnceleme
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 4

Sertifika Numarası: 1984-MDD-21-789

Aşağıda listesi verilen cihazların tasarım incelemesinin, Tıbbi Cihazlar Yönetmeliği 93/42/EEC Ek II Bölüm 4'e göre, konu oldukları ulusal yasaların gereksinimlerine uygun olarak tarafımızca gerçekleştirildiğini beyan ederiz. Aşağıda listesi verilen cihazların tasarımlarının Tıbbi Cihazlar Yönetmeliği 93/42/EEC Ek II Bölüm 4'ün ulusal yasalarda karşılığını bulan ilgili şartlarına uygun olduğunu onaylarız.

Kuruluş:

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CAD. 91A, ORTAHİSAR, TRABZON - TÜRKİYE

Ürün: KANSTAT®

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir (1) sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Bu sertifika kapsamında olan sınıf III ürünler için ayrıca Tıbbi Cihaz Yönetmeliği Tam Kalite Güvence Sistemi 93/42/AT Ek-II Bölüm 3 sertifikası da zorunludur.

Rapor No: M.6404.01
Son Geçerlilik Tarihi: 27 Mayıs 2024

17 Mayıs 2021, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

AT Sertifikası Eki:

Tasarım İnceleme

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 4

Sertifika Numarası: 1984-MDD-21-789

İlgili tıbbi cihazlar;

Ürün: KANSTAT®
Emilebilir Hemostat (Okside Edilmiş Rejenere Selüloz)
Tipleri: KANSTAT® Orj
KANSTAT® Fabric
KANSTAT® Felt
KANSTAT® Fibril
Model Numarası:

Çeşit	*Genişlik(cm)*	*Boy(cm)*
KANSTAT® Orj (KL)	1,25-10 cm	5-35 cm
KANSTAT® Fabric (KH)	2,5-15 cm	2,5-22,5 cm
KANSTAT® Felt (KW)	2,5-10 cm	5-10 cm
KANSTAT® Fibril (KB)	2,5-10 cm	5-10 cm

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

17 Mayıs 2021, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

EC Certificate
Design Examination According to
Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-789

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

Organization

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.

RİZE CAD. 91A, ORTAHİSAR, TRABZON - TURKEY

Product: KANSTAT®

The products defined at the enclosure which is the part of this certificate and contains one (1) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.6101.04
Expiry Date: 27 May 2024

17 May 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 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

CERTIFICATE

Enclosure of the EC Certificate:

Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-789

Concerned medical devices;

Product: KANSTAT®,
Absorbable Hemostat (Oxidized Regenerated Cellulose)
Types: KANSTAT® ORJ
KANSTAT® FABRIC
KANSTAT® FELT
KANSTAT® FIBRIL

Model Number:

Type	*Width(cm)*	*Length(cm)*
KANSTAT® Orj (KL)	1,25-10 cm	5-35 cm
KANSTAT® Fabric (KH)	2,5-15 cm	2,5-22,5 cm
KANSTAT® Felt (KW)	2,5-10 cm	5-10 cm
KANSTAT® Fibril (KB)	2,5-10 cm	5-10 cm

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

17 May 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 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

SERTİFİKA

Üretim Kalite Güvence

93/42/AT Tıbbı Cihaz Direktifi Ek V

Firma Adı : Honnes Sağlık ve Endüstriyel Ürünleri A.Ş.

Firma Adresi : Cumhuriyet Mah. Karayel Sokak No:14 Çayırova KOCAELİ / TÜRKİYE

İlgili Yönetmelikler ve Ekler : 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek V

Ürünler : Steril Hazır Pansuman Örtü(Nonwoven poliüretan) - Sınıf Is
Steril Göz Pedi - Sınıf Is
Steril Hemostatik Bası Bandı - Sınıf Is
Steril Kateter Sabitleme Bandı - Sınıf Is
- Nonwoven, şeffaf
- Poliüretan nonwoven pedli
- Şeffaf pedli
- Poliüretan pedli

GMDN : 34864, 11661

Sertifika Numarası	: M.2018.106.9658
Rapor Numarası	: MD.3508.YB
İlk Belgelendirme Denetimi	: 19.01.2016
Tescil Tarihi	: 10.05.2018
Yeniden Belgelendirme Denetimi	: 05.12.2018
Yeniden Belgelendirme Tarihi/No	: 27.02.2019/01
Revizyon Tarihi/No	: -
Geçerlilik Tarihi	: 07.02.2024

APPR 2292

UDEM Uluslararası Belgelendirme
Denetim Eğitim Merkezi
San. ve Tic. A.Ş.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek V, gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek v madde 4'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder. Belge kapsamında yer alan sınıf I ürünler ile ilgili UDEM'in sorumluluğu ürün steril ise, steril şartların güvence altına alınması ve sürdürülmesi ile ilgili imalat konuları; ölçüm fonksiyonlu ise, ürünlerin metrolojik gereklere uygunluğuyla ilgili imalat konuları ile sınırlıdır. Bu belgenin mülkiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. Ve Tic. A.Ş. 'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir. CE Markalamanın kullanımı üretici beyanı ile firma Sorumluluğundadır. Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udem.com.tr internet sayfasından kontrol edebilirsiniz.

CE 2292

Adres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TÜRKİYE
Tel: +90 312 443 03 90 **Faks:** +90 312 443 03 76
E-posta: info@udemltd.com.tr www.udem.com.tr

CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name : Honnes Sağlık ve Endüstriyel Ürünleri A.Ş.

Company Address : Cumhuriyet Mah. Karayel Sokak No:14 Çayırova KOCAELI / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Ready To Use Wound Dressing (Nonwoven Polyurethane) - Class I
Sterile Eye Pad - Class Is
Sterile Haemostatic Pressure Band - Class Is
Steril Catherer Fixation Band - Class Is
- Nonwoven, Transparent
- Polyurethane Nonwoven With Pad
- Transparent With Pad
- Polyurethane With Pad

GMDN : 34864, 11661

Certificate Number : M.2018.106.9658
Report Number : MD.3508.YB
Initial Assessment Date : 19.01.2016
Registration Date : 10.05.2018
Recertification Assessment Date : 05.12.2018
Reissue Date / No : 27.02.2019/01
Revision Date /No : -
Expiry Date : 07.02.2024

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

UDEM hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce 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 expiry date 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.

CE 2292

Addrres: 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 www.udem.com.tr

CERTIFICATE

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-21-730

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

KAPSAM SAĞLIK ÜRÜNLERİ
İNŞ. TAAH. TURİZM VE TİC. LTD. ŞTİ.

Cumhuriyet Mah. İsmet İnönü Cad. No:57 Çayırova/Kocaeli/Turkey

Products: Administration Sets Used with Pressure Infusion Device, Gravity Effect Infusion Sets, Extension Line, EVA Bag Protected From Light \ Transparent

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5949.01
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

06 January 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 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

CERTIFICATE

Enclosure of the EC Certificate:

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-21-730

Concerned medical devices;

Product Name: Administration Sets Used with Pressure Infusion Device, I.V. Infusion Multiplexer Set
Types: 4-Way I.V. Chemotherapy Administration Set, 2 Way I.V. Chemotherapy Administration Set, 1 Way I.V Chemotherapy Administration Set, I.V. Infusion Set, 2 Way I.V. Infusion Multiplexer Set, 4-Way I.V. Infusion Multiplexer Set

Product Name: Gravity Effect Infusion Sets
Types: I.V. Infusion Set with Flow Regulator, I.V. Infusion Set with 0.2 Micron Filter and Flow Regulator, I.V. Infusion Set with 1.2 Micron Filter and Flow Regulator

Product Name: IV Chemotherapy EVA Bag Light Protected, TPN EVA Bag Light Protected \ Transparent
Types: I.V. Chemotherapy Eva Bag Light Protected, TPN Eva Bag Light Protected, TPN Eva Bag Transparent, TPN Eva Bag Light Protected Dual Chamber, TPN Eva Bag Transparent Dual Chamber

Product Name: Extension Line

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

06 January 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 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

CERTIFICATE

AT Sertifikası
Üretim Kalite Güvence Sistemi
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-20-649

Aşağıda bahsi geçen kuruluşun üretim kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-V gereksinimlerine göre yapıldığını beyan ederiz. Üretim kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Fatih Mahallesi Çamlık Caddesi No:54 Gaziemir, İzmir, Türkiye

Ürünler: Steril Tek Kullanımlık Önlükler, Steril Tek Kullanımlık Örtüler, Steril Tek Kullanımlık Örtü Setleri, Steril Tek Kullanımlık Ekipman Kılıfları

Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No: M.5250.01

Son Geçerlilik Tarihi: 27 Mayıs 2024

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak steril şartların güvence altına alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle sınırlı olan kalite sistemini denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek V'deki uygulanabilir şartları karşıladığını tespit etmiştir.

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

08 Nisan 2020, İstanbul, Türkiye

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com

CERTIFICATE

EC Certificate
Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-20-649

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Fatih Mahallesi Çamlık Caddesi No:54 Gaziemir, İzmir, Turkey

Products: Sterile Disposable Gowns, Sterile Disposable Drapes, Sterile Disposable Drape Packs, Sterile Disposable Equipment Covers

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

Report Number: M.5250.01
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V.

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

08 April 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 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

EC Certificate
Full Quality Assurance System

Certificate No.:
12853-2018-CE-ARE-NA-PS

Project No.:
PRJC-572112-2017-PRC-ARE

Valid Until:
02 August 2023

This is to certify that the quality system of:

Yücel Medikal
ve Tekstil Ürünleri san.Tic.Ltd.Şti.
Selahaddin Eyyubi Mah.1612 Sok.No:19 34850 Esenyurt, Istanbul, Turkey

For design, production and final product inspection/testing of:

Sterile Absorbale Haemostatic Gelatin Sponge

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 02 August 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Sholeh Gheissar

Sholeh Gheissar

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **12853-2018-CE-ARE-NA-PS**

Project No.: **PRJC-572112-2017-PRC-ARE**

Valid Until: **02 August 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	**2018-08-02**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Absorbale Haemostatic Gelatin Sponge	**CLINISPONGE Absorbale Haemostatic Gelatin Sponge** Standart 80x50x10 mm / Dial 30x30x10 mm Standart 70x50x10 mm / Tampon 80x Ø 30 mm Special 80x50x1mm / Dental 10x10x10 mm Special 70x50x1 mm / Dental 14x7x7 mm Film 200x70x0.5 mm / Powder 1 gr	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 12854-2018-CE-ARE-NA-PS

Sites covered by this certificate

Site Name	Address
Yücel Medikal	Selahaddin Eyyubi Mah.1612 Sok.No:19 34850 Esenyurt, Istanbul, Turkey

EU Representative

Yuecel Senol, Simmeringer Haupt Str. 81/1/6 1110, Vienna, Austria

Terms and conditions

EC Certificate
Full Quality Assurance System

Certificate No.: **12853-2018-CE-ARE-NA-PS**

Project No.: **PRJC-572112-2017-PRC-ARE**

Valid Until: **02 August 2023**

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Digitally signed by Cojocaru Vera
Date: 2022.01.19 12:09:20 EET
Reason: MoldSign Signature
Location: Moldova