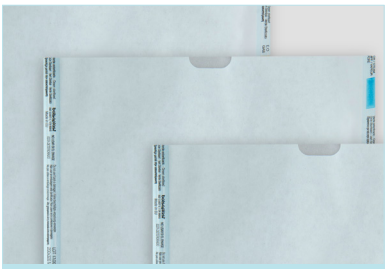
MEDICAL PACKAGING

BOLSAPACK • PACKAGING FOR STEAM/EO/FORMOL

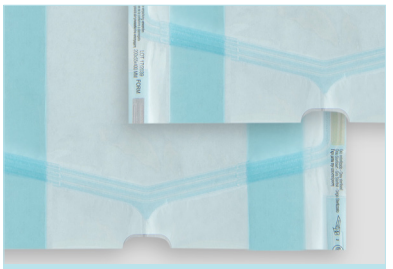
Pouches and rolls, manufactured with 60 g/m^2 medical paper and a plastic film (blue coloured). Indicators for Steam/EO/Formol are also printed in packaging.

PAPER/FILM FLAT BAG

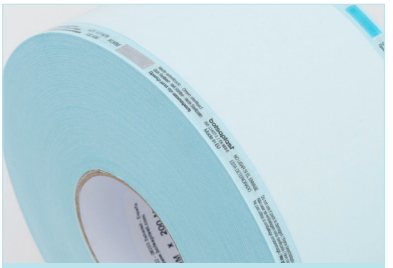
Code	Sizes		U/Box	Box/cm	Box/Kg
MBO1025	75 x 150 mm	3 x 6”	2.700	17 x 25 x 17	3,2
MBO1000	75 x 210 mm	3 x 8”	2.500	31 x 29 x 11	4,2
MBO1001	75 x 280 mm	3 x 11”	2.400	31 x 29 x 11	5,7
MBO1003	100 x 200 mm	4 x 8”	2.400	41 x 29 x 11	5,7
MBO1004	100 x 240 mm	4 x 9”	2.400	41 x 29 x 11	6,7
MBO1005	100 x 280 mm	4 x 11”	2.400	41 x 29 x 11	7,7
MBO1026	100 x 300 mm	4 x 12”	2.500	41 x 43 x 11	8,7
MBO1006	100 x 420 mm	4 x 17”	2.400	41 x 43 x 11	11,7
MBO1022	100 x 580 mm	4 x 23”	2.000	41 x 59 x 11	13,7
MBO1007	150 x 210 mm	6 x 8”	2.000	32 x 43 x 11	7,2
MBO1008	150 x 280 mm	6 x 11”	2.000	31 x 57 x 11	9,7
MBO1009	150 x 320 mm	6 x 13”	2.000	37 x 65 x 11	11,2
MBO1010	150 x 360 mm	6 x 14”	2.000	37 x 65 x 11	12,7
MBO1021	150 x 400 mm	6 x 16”	1.200	32 x 43 x 11	8,2
MBO1011	200 x 320 mm	8 x 13”	1.800	37 x 65 x 11	13,2
MBO1012	200 x 360 mm	8 x 14”	1.800	37 x 65 x 11	14,7
MBO1013	200 x 420 mm	8 x 17”	1.200	41 x 43 x 11	11,2
MBO1023	200 x 500 mm	8 x 20”	1.200	41 x 59 x 11	14,5
MBO1014	250 x 360 mm	10 x 14”	1.200	51 x 51 x 11	12,7
MBO1015	250 x 420 mm	10 x 17”	1.200	51 x 51 x 11	15,2
MBO1016	250 x 500 mm	10 x 20”	1.200	51 x 51 x 11	17,7
MBO1017	300 x 420 mm	12 x 17”	600	32 x 43 x 11	9,2
MBO1018	300 x 500 mm	12 x 20”	600	31 x 57 x 11	10,2
MBO1024	300 x 580 mm	12 x 23”	700	41 x 59 x 11	13,9
MBO1019	400 x 580 mm	16 x 23”	600	41 x 59 x 11	15,7



Paper/Film flat bag



Paper/Filmgusset bag



Paper/Film flat roll

PAPER/FILM GUSSET BAG

Code	Sizes		U/Box	Box/cm	Box/Kg
MBF1202	200 x 55 x 400 mm	8 x 2” x 16”	600	41 x 43 x 11	6,7

C. Bernat Metge, 110-112. 08205 - Sabadell (Barcelona) SPAIN +34 937 117 361 medical@bolsaplast.com www.bolsaplast.com

MEDICAL PACKAGING

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Pouches and rolls, manufactured with 60 g/m^2 medical paper and a plastic film (blue coloured). Indicators for Steam/EO/Formol are also printed in packaging.

PAPER/FILM SELFSEALING BAG

Code	Sizes		U/Case	U/Box	Box/cm	Box/Kg
MBA1080	75 x 200 mm	3 x 8”	200	1.200	17 x 25 x 17	2,4
MBA1081	90 x 200 mm	4 x 8 ”	200	1.200	22 x 28 x 17	3,2
MBA1082	90 x 230 mm	4 x 9”	200	1.200	22 x 28 x 17	4,3
MBA1084	100 x 240 mm	4 x 9”	200	1.200	23 x 29 x 17	4,2
MBA1085	130 x 250 mm	5 x 10”	200	1.200	28 x 30 x 17	5,7
MBA1086	130 x 330 mm	5 x 13”	200	1.200	28 x 38 x 17	7,3
MBA1087	140 x 280 mm	6 x 11”	200	1.200	30 x 33 x 17	6,7
MBA1088	200 x 330 mm	8 x 13”	200	800	42 x 38 x 12	7,2
MBA1089	250 x 400 mm	10 x 16”	200	800	52 x 45 x 12	10,7
MBA1090	300 x 390 mm	12 x 15”	***	400	32 x 43 x 11	6,6
MBA1091	300 x 450 mm	12 x 18”	***	400	31 x 50 x 11	6,7

Paper/Film selfsealing bag

Selfsealing tape


Paper/Film gusset roll

PAPER/FILM FLAT ROLL

Code	Sizes		U/Box	Box/cm	Box/Kg
MRP1040	50 mm x 200 m	2” x 656 Feet	6	31 x 25 x 23	7,2
MRP1041	75 mm x 200 m	3” x 656 Feet	4	31 x 25 x 23	7,2
MRP1042	100 mm x 200 m	4” x 656 Feet	4	43 x 26 x 23	9,7
MRP1043	125 mm x 200 m	5” x 656 Feet	4	44 x 32 x 23	11,7
MRP1044	150 mm x 200 m	6” x 656 Feet	4	44 x 32 x 23	13,7
MRP1045	200 mm x 200 m	8” x 656 Feet	2	43 x 26 x 23	9,2
MRP1046	250 mm x 200 m	10” x 656 Feet	2	43 x 26 x 23	11,2
MRP1047	300 mm x 200 m	12” x 656 Feet	2	44 x 32 x 23	13,7
MRP1050	350 mm x 200 m	14” x 656 Feet	1	41 x 21 x 22	8,2
MRP1048	400 mm x 200 m	16” x 656 Feet	1	41 x 21 x 22	9,2
MRP10491	500 mm x 100 m	20” x 328 Feet	1	52 x 18 x 18	5,7

PAPER/FILM GUSSET ROLL

Code	Sizes		U/Box	Box/cm	Box/Kg
MRF1059	75 x 25 mm x 100 m	3 x 1” x 328 Feet	4	31 x 25 x 23	4,7
MRF1060	100 x 40 mm x 100 m	4 x 2” x 328 Feet	4	43 x 26 x 23	6,7
MRF1061	150 x 40 mm x 100 m	6 x 2” x 328 Feet	4	44 x 32 x 23	9,2
MRF1062	200 x 60 mm x 100 m	8 x 2” x 328 Feet	2	43 x 26 x 23	6,2
MRF1063	250 x 60 mm x 100 m	8 x 2”x 328 Feet	2	43 x 26 x 23	7,2
MRF1064	300 x 80 mm x 100 m	8 x 2” x 328 Feet	1	31 x 25 x 23	4,7
MRF1065	400 x 80 mm x 100 m	16 x 3” x 328 Feet	1	41 x 21 x 22	5,7

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KATETER JEL

CATHETER GEL / GEL POUR CATHÉTER / GEL DE CATÉTER

107.0007
12 ml.

STERILE R

107.0005
6 ml.

107.0014
12,5 ml

TR Özellikler & Kullanım Şekli

Lidokain içeren Konix Steril Kateter Jeli, üretraya kateter, sistoskopi ve/veya başka bir tıbbi alet uygulamadan önce kullanılan steril, berrak, suda çözünen kaydırıcı bir jeldir. Jelin en önemli fonksiyonu kateter veya başka bir tıbbi alet ile üretral mukoza arasında kaydırıcı bir tabaka oluşturarak üretrayı kaplamasıdır. Lidokain içeren Konix Steril Kateter Jelin uygulamasından önce üretral manipulasyonla bağlantılı olan ağrının giderilmesinde yardımcı olmak amacıyla üretranın kaydırılması için kullanılır. Ayrıca anestezik etkisi ile ağrısız bir kateterizasyon sağlar. Konix Steril Kateter Jeli'nin antiseptik etkisi iatrojenik kontaminasyondan dolayı üst bölümü ve mesanede oluşabilecek enfeksiyonlardan hastayı korur.

Saklama Koşulları: 5-30°C'nin arasında ve güneş ışığından uzakta, serin bir yerde muhafaza ediniz.

FR Propriétés & Utilisation

Cahéter stérile est une lidocaïne stérile contenant du gel clair et soluble dans l'eau qui est utilisé avant l'application de cathéter ou d'autres instruments médicaux sur l'urètre, pour des examens cystoscopiques ou autres. Recouvrir l'urètre en générant une couche lisse entre la muqueuse urétrale et le cathéter ou d'autres instruments médicaux c'est est la plus importante fonction du gel. Konix Gel pour cathéter stérile comprenant de lidocaïne, est utilisé avant l'intervention afin de protéger l'urètre pour atténuer la douleur liée à la manipulation urétrale. En outre, la pose du cathéter devient indolore grâce à son effet anesthésique. L'effet antiseptique du gel protège les patients d'une infection éventuelle qui pourrait se déclarer dans la partie supérieure et de la vessie et due à la contamination iatrogène.

Stockage: Conserver dans un endroit frais et sec entre 5 - 30 ° C à l'abri des rayons soleil.

EN Properties & Use

Konix Sterile Catheter Gel is a sterile lidocaine contained, clear and water-soluble sort of gel which is used before applying cathether, cystoscopy and/or else medical instrument to urethra. Covering urethra by generating a slick layer between urethral mucosa and catheter or else medical instrument is the most significant function of the gel. Catheter Gel, including Lidocaine, inside, is used before the application in order to replace urethra for the purpose of dulling the pain related to urethral manipulation. Moreover, it provides an indolent catheterization with its anaesthetic effect. Antiseptic effect of the gel insulates patients from the potential infections that may occur within the upper part and urinary bladder due to iatrogenic contamination.

Storage: Store in a cool and dry environment between 5–30 °C away from direct sunlight.

ES Características y Modo de Empleo

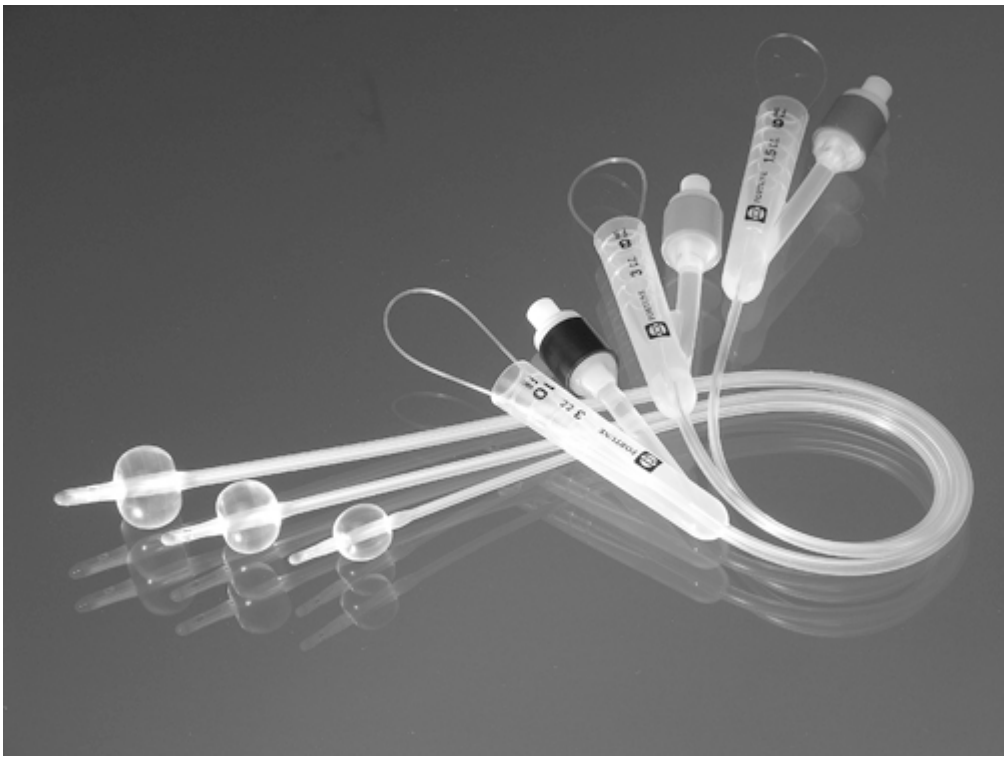
Catéter contiene lidocaína y es un gel lubricante de tipo estéril, transparente y soluble en agua, que se utiliza antes de aplicar el catéter, la cistoscopia y/o otro dispositivo médico a la uretra. La función más significativa del gel es cubrir la uretra mediante la generación de una capa resbaladiza entre la mucosa de la uretra y el catéter u otro dispositivo médico. Konix Gel Estéril de Catéter que contiene lidocaína se utiliza antes, para remplazar la uretra con el fin de evitar el dolor relacionado con la su manipulación. Además, proporciona un cateterismo indolente gracias a su efecto anestésico. El efecto antiséptico de Konix Gel Estéril de Catéter protege a los pacientes de las posibles infecciones que pueden originarse dentro de la parte superior de la vejiga y que es debida a la contaminación iatrogénica.

Almacenamiento: Conservar en ambiente seco y fresco entre 5-30° C fuera del alcance directo de la luz solar

Fortune® Silicone 2 way Foley balloon Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent medical grade silicone tube allows easy visual inspection and fluid observation.
- X-ray opaque line allows for confirmation of intubated tube using X-ray.
- Soft and uniformly inflated balloon makes the tube sit well against the bladder.
- Smooth round shaft can minimize trauma during insertion and withdrawal.
- 6FR, 8FR and 10FR Pediatric Foley Catheter has disposable stylet for easy insertion.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.
- Recommended usage up to 90dyas for 4833 series, of which balloon is more durable; recommended usage up to 29days for 182x/1856/1830/4822/4856 series.

(A) Pediatric
(B) Standard, 5-10 cc/ml
(C) Standard, 20-30 cc/ml
(D) Female
(E) Catheter Spigot
(F) Tiemann Tip



0086

Specifications

2-Way Foley Balloon Catheter, Pediatric:

2-Way Foley Balloon Catheter, Standard, 5-10 cc/ml:

REF. No.	Size	Balloon	Length	Description
1822-0512	12 FR	5-10 cc/ml	420 mm	X-ray opaque line Catheter spigot
1822-0514	14 FR			
1822-0516	16 FR			
1822-0518	18 FR			
1822-0520	20 FR			
1822-0522	22 FR			
1822-0524	24 FR			
1822-0526	26 FR			

1822-05XX

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
[illegible]

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 170030

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **TURKUAZSAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLERİSAN.VE TİC, LTD. ŞTİ.**
Yakuplu Mah. Birlik Cad No:34/3 Beylikdüzü, İstanbul, Turkey

for design, manufacturing and final inspection of medical device(s)

Catheter gel with lidocain - class III

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **203303-01 of 30.5.2017**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 05.06.2017 with validity until 04.06.2022.
The validity of this Certificate is limited until: 04.06.2022

05.06.2017

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

203303-01

bolsaplast

ISO 9001 BUREAU VERITAS Certification

ISO 13485 BUREAU VERITAS Certification

CERTIFICATION
DECLARATION OF CE CONFORMITY – Directive 93/42/CE

BOLSAPLAST S.L., supplies under CE mark, the following products:

- Paper/Film Flat Bags (MBO)
- Paper/Film Selfsealing Bags (MBA)
- Paper/Film Gusset Bags (MBF)
- Paper/Film Flat Reels (MRP)
- Paper/Film Gusset Reels (MRF)
- Tyvek®/Film Flat Bags (MBT)
- Tyvek®/Film Flat Reels (MRT)
- Steam Tape (MCV)
- Bolsacrepe (MCREP)
- Bolsacover (MBCOVER)

All our products are adequate for hospital using, in sterilization processes of medical-surgical products and similar materials.

Products above mentioned are produced in conformity with EN 868-2/3/4/5 and ISO 11607-1, about packaging and systems for medical products to be sterilized.

Our products meet essential requirements in Annex I of the EEC/93/42 Directive and they belong to Class 1 non sterile packaging.

According to our quality system, all necessary processes are took to agree with manufacturing and service parameters established by our quality management system under norm ISO 9001-2008 and ISO13485-2013. Surveillance process and technical information are developed to also agree with norms.

Signature : Jaume Pares Criville
Date : 31st March 2017

bolsaplast
BOLSAPLAST, S.L. - CIF: B-08808990
Domicilio Fiscal: C/ BERNAT METGE, 110-112
Correspondencia: C/ BERNAT METGE, 112
08205 - SABADELL (Barcelona) SPAIN
Tel.: 34 93 711 73 61 - Fax: 34 93 712 23 55

DECLARATION OF CONFORMITY

MANUFACTURER:	FORTUNE MEDICAL INSTRUMENT CORP. 6FL., NO. 29, SEC. 2, JHONGJHENG E. RD., DANSHUEI DIST, NEW TAIPEI CITY 251, TAIWAN
FACILITY:	FORTUNE MEDICAL INSTRUMENT CORP. NO.256,CHANGCHUN 2ND RD. JHONGLI DIST., TAOYUAN CITY 320, TAIWAN
EUROPEAN REPRESENTATIVE:	PRIM, S.A. C/F 15, POL. IND. NO. 1, 28938 MOSTOLES, MADRID, SPAIN TEL: 34 91 334 4334 FAX: 34 91 334 2490
PRODUCT:	Silicone Foley Balloon Catheter
NO. OF PRODUCT:	1821, 1822, 1823, 1824, 1827, 1856, 1830, 4822, 4856, 4833 Series
CLASSIFICATION:	Class IIb, Rule 5 (According to Annex IX of the MDD)
GMDN CODE NO. :	34917
CONFORMITY ASSESSMENT ROUTE:	Annex II.3

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	MDD 93/42/EEC, INCLUDING 2007/47/EC, EN ISO 9001/ EN ISO 13485, EN 980, EN ISO 15223-1, EN ISO 11135, EN 1616, ISO 10993
NOTIFIED BODY:	British Standard Institution Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom
(EC) CERTIFICATE:	CE 588902
START OF CE MARKING:	Nov. 6, 1998
MANAGEMENT REPRESENTATIVE:	Lien Ping Wang
SIGNATURE:	L. P. Wang
PLACE, DATE OF ISSUE:	Taiwan, Jan. 19, 2016

BUREAU VERITAS
Certification

Certificación

Certification

Concedida a / Awarded to

BOLSAPLAST SL

C/ BERNAT METGE,110-112
08205 SABADELL
SPAIN

Bureau Veritas Certification certifica que el Sistema de Gestión ha sido auditado y encontrado conforme con los requisitos de la norma:

Bureau Veritas Certification certifies that the Management System has been audited and found to be in accordance with the requirements of standard:

NORMA / STANDARD

UNE EN ISO 13485:2013

El Sistema de Gestión se aplica a:

Scope of certification

FABRICACIÓN Y COMERCIALIZACIÓN DE EMBALAJE DESTINADO A PRODUCTOS MÉDICOS.

MANUFACTURING AND MARKETING OF PACKAGING FOR MEDICAL PRODUCTS.

Número del certificado *Certificate Number*	**ES077880-1**
Aprobación original : *Original approval date :*	***22/01/2014***
Certificado en vigor: *Effective date:*	***22/01/2017***
Caducidad del certificado: *Certificate expiration date:*	***21/01/2020***

Directora de Certificación / Certification Manager

Este certificado está sujeto a los términos y condiciones generales y particulares de los servicios de certificación
This certificate is valid, subject to the general and specific terms and conditions of certification services

Entidad de Certificación / Certification Body: Bureau Veritas Iberia S.L.
C/ Valportillo Primera 22-24, Edificio Caoba, Pol. Ind. La Granja, 28108 Alcobendas - Madrid, Spain

Certificate

SERTİFİKA

TÜRCERT Sertifikasyon Merkezi
iş bu belge ile/TÜRCERT Certification Body
with this document.

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TIC. A.Ş.

YAKUPLU MAH. BİRLİK CAD. NO:32/1 BEYLİKDÜZÜ İSTANBUL TÜRKİYE

şirketinin;/ of the company

RÖNTGEN SOLÜSYONLARI, TIBBİ CİHAZ DEZENFEKTANLARI VE MEDİKAL CİHAZLAR İÇİN STERİL BUĞU ÖNLEYİCİ SOLÜSYON, STERİL VE STERİL OLMAYAN KAYGANLAŞTIRICI JELLER, DOĞUM JELLERİ, STERİL VE STERİL OLMAYAN ULTRASON JELLERİ, STERİL VE STERİL OLMAYAN BURUN SOLÜSYONLARI, BİT ŞAMPUANI VE SPREYİ VE SMEAR DOKU SABİTLEYİCİ SPREYİNİN TASARIMI, ÜRETİMİ VE SATIŞI

MANUFACTURING AND SALES OF MEDICAL X-RAY SOLUTIONS, MEDICAL DEVICE DISINFECTANT, STERILE ANTIFOG SOLUTION FOR MEDICAL DEVICES, STERILE AND NON-STERILE LUBRICANT GELS, OBSTETRIC GEL, STERILE & NON-STERILE ULTRASOUND GELS, STERILE & NON-STERILE NASAL SOLUTIONS, ANTI-LICE AND NITS SHAMPOO AND SPRAY AND SMEAR SPRAY

belirlenen standardın uygulanması konusunda tıbbi cihazlar için yönetim sistemi yürürlüğe koyduğunu ve uygulamakta olduğunu taahhüt eder./ Effective medical devices management system and guarenteesthat you put in to apply

2018101013284-01MDMS Sayılı rapordaki inceleme ile/
2018101013284-01MDMSwith the nr. examination report;

TS EN ISO 13485:2016

şartlarının sağlanmış olduğu kanıtlanmıştır, iş bu sertifika yıllık ara denetimlerinin yapılması kaydıyla **08.08.2021** tarihine kadar geçerlidir./ Its proven that requirements are provided. This certificate is valid until **08.08.2021** with the condition of surveillance audits done

Sertifika Kayıt No/ Certificate Registration Nr : 2018101013284-01
Sertifika Yayın Tarihi / Date of Issue : 10.10.2018
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 08.08.2021

TÜRCERT

Türcert A.Ş.
Belgelendirme Bölümü Adına

ÖSAS
ÖSTERREICH
Spezielle Akkreditierung Service
austria
ÖSAS Ö-41

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME ANONİM ŞİRKETİ
Adres : Sanayi Mh. Atatürk Cd. No 57/17 Güngören / İstanbul - Türkiye
Telefon: 0 212 909 35 90 - 0 312 500 00 10 www.turcert.com