Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. **30** din **17.09.2023**

Solicitantul **Comerț-Magor S.R.L.**, cu sediul **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, tel./fax: **022742200/022743931**, e-mail **veracojocaru@mail.ru**, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Clasa de risc	Cod GMDN	Producator
ETH VM101	Banda de fixare canula endotraheala	Endotracheal Cannula Fixation Band	3cm x 55 cm	Is, Rule I	35815	MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE TİC. LTD. ŞTİ.

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivele fabricate
b) certificatul de conformitate CE valabil pentru dispozitivele fabricate
c) actul prin care producătorul își desemnează reprezentantul

Data **26.06.2023** Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Cojocaru Vera
Date: 2023.09.17 12:42:38 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **Comerț-Magor S.R.L.**, cu sediul în **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Clasa de risc	Cod GMDN	Producator
ETH VM101	Banda de fixare canula endotraheala	Endotracheal Cannula Fixation Band	3cm x 55 cm	Is, Rule I	35815	MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE TİC. LTD. ŞTİ.

Sunt autentice și corespund realității.

Administrator Cojocaru Vladimir *Semnătura* _____

Data 17.09.2023

MEDİKOKİM®

TIBBİ ve KİMYEVİ MALZEME
SAN. TİC. LTD. ŞTİ

POWER OF ATTORNEY

The Company **Medikokim Tıbbi ve Kimyevi Malzeme San. ve Tic. Ltd. Şti.,** located at İkitelli O.S.B. Demirciler San. Sit. B-7 Blok No:157 Başakşehir / ISTANBUL / TURKEY hereinafter called - «The Manufacturer», duly represented by the General Manager, **Muhammed PEZÜK**, acting under and by virtue of the Articles of Association.

By this power of attorney authorizes:

The Company **"Comert-Magor" S.R.L.,** Registration number: 1003600022518 located at str. Bucuriei 1, mun. Chisinau, MD-2004, Moldova, hereinafter called - «An authorized representative of the manufacturer».

-To represent the interests of The Manufacturer on the circulation of medical devices produced by **Medikokim Tıbbi ve Kimyevi Malzeme San. ve Tic. Ltd. Şti.,** on the territory of the Republic of Moldova.

- To register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.;

- To conduct negotiations;

- To sign the statements, applications, contracts and other necessary documents, including financial, with the purpose of state registration and conformity assessment of medical devices;

- To provide with technical, operational and other documentation and materials required for the state registration and conformity assessment of the medical device, to give clarifying explanation;

- To initiate changes to the registration certificate for medical devices, if it is necessary;

- To provide with other necessary information and documents for the state registration and conformity assessment of medical device;

- To make payments for the services;

- To perform other necessary actions related to the registration or conformity assessment of the medical device;

- To get the Registration certificate issued in the name of **Medikokim Tıbbi ve Kimyevi Malzeme San. ve Tic. Ltd. Şti.**

This power of attorney is granted for **5 years**, with a right of substitution.

Medikokim Tıbbi ve Kimyevi Malzeme San. ve Tic. Ltd. Şti. Date 08.03.2023

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. TİC. LTD. ŞTİ.
İkitelli O.S.B. Demirciler San.Sit. B7 Blok No :157 Başakşehir / İstanbul
İkitelli V.D. 613 007 8790 Tic.Sicil no : 319018
Tel :0212 549 57 78 / Fax :0212 549 57 79

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Production Quality Assurance Certificate

Directive 93/42/EEC on Medical devices, Annex V (Class I devices in sterile conditions and sterilised systems or procedure packs)

Notified Body	:	Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Türkiye (NB 1783)
Company Name	:	Medikokim Tıbbi ve Kimyevi Malzeme San Tic Ltd Şti
Company Address	:	İkitelli OSB Demirciler San. Sitesi B7 blok no:157 Başakşehir 34306 Istanbul Turkey
Manufacturing Site	:	İkitelli OSB Eski Turgut Özal Bulvari Mehmet Çakici Iş Merkezi No:17/701 Başakşehir / Istanbul Turkey
Scope	:	Sterile Fixing, Protective, Supporting Bands
GMDN Code	:	12094 ,12102, 12097, 36053, 35752,35815, 11291,35063,12102 41232,16513,36053, 35063
Classification Rule	:	Rule 1 , Class 1S
Inspection Report Number	:	1181-MDD-066/2021-01
First Issue Date	:	27.02.20218
Validity Date	:	27.02.2023

The manufacturer's quality system is inspected in accordance with Annex V of the Medical Device Directive restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions and the quality system meets the requirements of Medical Device Directive Annex V. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex V Section 4.

Certificate No: 1783- MDD-082

TÜRK STANDARTLARI ENSTİTÜSÜ * DİREKTİFLER MÜDÜRLÜĞÜ * 1783 TSE TURKISH STANDARDS INSTITUTION

Fırat Hacıoğlu

Deputy Director of Directives

ANKARA Rev03, 25.05.2021

Please check the validity of certificate from TSE's web page "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open"

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
This certificate cannot be altered, partially dublicated or ereased for misunderstanding.

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Production Quality Assurance Certificate Certification History

Directive 93/42/EEC on Medical devices, Annex V (Class I devices in sterile conditions and sterilised systems or procedure packs)

Certificate No: 1783-MDD-082, Rev 03

CERTIFICATE HISTORY		
Date	**Revision Number**	**Reason of Revision**
27.02.2018	Rev 00	-
31.07.2019	Rev 01	Template change
20.05.2021	Rev 02	Manufacturing site change
25.05.2021	Rev 03	Editorial correction

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
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TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Production Quality Assurance Certificate Scope Attachment

Directive 93/42/EEC on Medical devices, Annex V (Class I devices in sterile conditions and sterilised systems or procedure packs)

Certificate No: 1783-MDD-082, Rev 03

S.N	Label Name	Brand name	Model - Size Name (cm)	Product Internal Reference No
1	Adult Limb Holder - Hand	FESTERMED	5cm*25cm	ALH 2001
2	Adult Limb Holder - Foot	FESTERMED	5cm*40cm	ALH 2002
3	Adult Limb Holder - Hand & Foot	FESTERMED	5cm*25cm & 5cm*40cm	ALH 2004
4	Adult Limb Holder - Leg	FESTERMED	6,5cm*65cm	ALH 2003
5	Adult Limb Holder - Hand & Foot	FESTERMED	7,5cm*34cm	ALH 2006
6	Adult Limb Holder - Hand & Foot	FESTERMED	7,5cm*34cm	ALH 2007
7	Adult Limb Holder - Wrist	FESTERMED	7,5cm*44cm	TC 2009
8	Adult Limb Holder - Hand & Foot	FESTERMED	7cm*25cm	ALH 2011
9	Adult Limb Holder - Hand & Foot	FESTERMED	7cm*25cm	ALH 2012
10	Ear Support Band	DECKELMED	4,5cm*50cm	EPH 7001
11	Ear Support Band	DECKELMED	5cm*59cm	EPH 7002
12	Wrist Holder	FİXERBOARD	2,5cm*10,5cm	LHC01
13	Wrist Holder	FİXERBOARD	3,5cm*12cm	LHC02
14	Wrist Holder	FİXERBOARD	4,5cm*13cm	LHC03
15	Wrist Holder	FİXERBOARD	6,5cm*14,5cm	LHC04
16	Wrist Holder	FİXERBOARD	7,5cm*18,5cm	LHC05
17	Wrist Holder	FİXERBOARD	9cm*23cm	LHC06
18	Wrist Holder	FİXERBOARD	3cm*9cm	LHB01
19	Wrist Holder	FİXERBOARD	4cm*10cm	LHB02
20	Wrist Holder	FİXERBOARD	4cm*12cm	LHB03
21	Nasal Cannula Fixation	NASOMED	6,5cm*38cm	NTH 5001
22	Nasal Cannula Fixation	NASOMED	3cm*65cm	NTH 5002

www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

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23	Nasal Cannula Fixation	NASOMED	2,5cm*30cm	NTH 5001 TP
24	Phototherapy Eye Protector	SCHÜTZERMED	4cm*24,5cm	PEB 301
25	Phototherapy Eye Protector	SCHÜTZERMED	4,7cm30cm	PEB 302
26	Phototherapy Eye Protector	SCHÜTZERMED	5,5cm*32,5cm	PEB 303
27	Phototherapy Eye Protector	SCHÜTZERMED	2,2cm*11,5cm	PEB STC 301
28	Phototherapy Eye Protector	SCHÜTZERMED	2,6cm*16,5cm	PEB STC 302
29	Phototherapy Eye Protector	SCHÜTZERMED	3cm*19cm	PEB STC 303
30	Phototherapy Eye Protector	SCHÜTZERMED	7cm*23cm	PEB YT 301
31	Phototherapy Eye Protector	SCHÜTZERMED	8cm*27cm	PEB YT 302
32	Phototherapy Eye Protector	SCHÜTZERMED	9cm*32cm	PEB YT 303
33	Phototherapy Eye Protector	SCHÜTZERMED	6,5cm*25cm	PEB TPD 301
34	Endotrachael Tube Holder	STAENDERMED	3cm*50cm	ETHCLPTP
35	Endotrachael Tube Holder	STAENDERMED	3cm*55cm	ETH CLPM101
36	Endotrachael Tube Holder	STAENDERMED	3cm*65cm	ETH CLPM102
37	Endotrachael Tube Holder	STAENDERMED	3cm*55cm	ETH SC 101
38	Endotrachael Tube Holder	STAENDERMED	3cm*43cm	ETH SCTP
39	Endotrachael Tube Holder	STAENDERMED	3cm*65cm	ETH SC 102
40	Endotrachael Tube Holder	STAENDERMED	3cm*45cm	ETH SCM201
41	Endotrachael Tube Holder	STAENDERMED	3cm*55cm	ETH SCM202
42	Endotrachael Tube Holder	STAENDERMED	3cm*65cm	ETH SCM203
43	Endotrachael Tube Holder	STAENDERMED	3cm*55cm	ETHVM101
44	Endotrachael Tube Holder	STAENDERMED	3cm*65cm	ETHVM102
45	Endotrachael Tube Holder	STAENDERMED	3cm*45cm	ETH 201
46	Endotrachael Tube Holder	STAENDERMED	3cm*55cm	ETH 202
47	Endotrachael Tube Holder	STAENDERMED	3cm*65cm	ETH 203
48	Endotrachael Tube Holder	STAENDERMED	3cm*50cm & 3cm*45cm	ETH TP

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This certificate cannot be altered, partially dublicated or ereased for misunderstanding.

49	Nasal Pad Support Band	STOPPERMED	2,5cm*25cm	NTH 01
50	Trachestomy Tube Fixation Band	TRAEGERMED	3,5cm*23cm	TCHS01
51	Trachestomy Tube Fixation Band	TRAEGERMED	3,5cm*44,5cm	TCHS02
52	Trachestomy Tube Fixation Band	TRAEGERMED	3cm*56cm	TCHS03
53	Trachestomy Tube Fixation Band	TRAEGERMED	3,5cm*23cm	TCH R 01
54	Trachestomy Tube Fixation Band	TRAEGERMED	3,5cm*44,5cm	TCH R 02
55	Trachestomy Tube Fixation Band	TRAEGERMED	3cm*56cm	TCH R 03
56	Trachestomy Tube Fixation Band	TRAEGERMED	2,5cm*37cm	TCHSTP
57	Trachestomy Tube Fixation Band	TRAEGERMED	2,5cm*37cm	TCH R TP
58	Adult Limb Holder - Hand	TSM	3cm*40cm	TSM UYESB 2001
59	Adult Limb Holder - Foot	TSM	3cm*55cm	TSM UYASB 2002
60	Adult Limb Holder - Hand	TSM	5cm * 25cm	TSM YESB 2001
61	Adult Limb Holder - Foot	TSM	5cm*40cm	TSM YASB 2002
62	Adult Limb Holder - Leg	TSM	4cm*19,5cm	TSM YBSB 2003
63	Baby Limb Holder	TSM	4cm*19,5cm	TSM UBEASB 3001
64	Phototherapy Eye Protector	TSM	4cm*24,5cm	TSM 301
65	Phototherapy Eye Protector	TSM	4,7cm30cm	TSM 302
66	Phototherapy Eye Protector	TSM	5,5cm*32,5cm	TSM 303
67	Endotrachael Tube Holder	TSM	3cm*65cm	TSM ETT 102
68	Endotrachael Tube Holder	TSM	3cm*55cm	TSM ETT 101
69	Trachestomy Tube Fixation Band	TSM	3,5cm*23cm	TSM TKT 01
70	Trachestomy Tube Fixation Band	TSM	3,5cm*23cm	TSM 01 TP
71	Trachestomy Tube Fixation Band	TSM	3,5cm*44,5cm	TSM 02 TP
72	Trachestomy Tube Fixation Band	TSM	3cm*56cm	TSM 03 TP

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Türkçeden İngilizceye çeviridir

REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL DEVICES INSTITUTION OF TURKEY

Number : E-61749811-511.99-1126751
Theme : 2023-KK-1 Date: 05.06.2023

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE TİC. LTD. ŞTİ.
İkitelli O.S.B. Demirciler San. Sitesi B7 Blok No:157 34306 Başakşehir / İSTANBUL

Subject : Your letter dated 22.05.2023 and numbered E-48535386-511.01.99-2379338

Your request in the letter of interest for the extension of the validity of the EC certificates with the numbers 1783-MDD-079, 1783-MDD-080, 1783-MDD-081 and 1783-MDD-082 has been examined.
Regulation (EU) No 2023/607 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions for certain medical devices and in vitro diagnostic medical devices in order to reduce the risk of non-delivery of medical devices' was published in the Official Journal of the EU on 20 March 2023 and applies from 20 March 2023.
Im Rahmen der Angleichung an das geltende Medizinprodukterecht der EU; Parallel zur Verordnung (EU) Nr. 2023/607 des Europäischen Parlaments und des Rates wurden unsere Verordnungen mit dem Titel "Verordnung zur Änderung der Verordnung über Medizinprodukte" und "Verordnung zur Änderung der Verordnung über Medizinprodukte für In-vitro-Diagnosezwecke" im Amtsblatt vom 2.4.2023 veröffentlicht und die genannten Änderungen in der Verordnung über Medizinprodukte und der Verordnung über Medizinprodukte für In-vitro-Diagnosezwecke vorgenommen.
In this regard, our notice entitled "Notice on the implementation of the provisions of Regulation (EU) No. 2023/607 (EU) No. 2023/KK-1" explaining the procedures and principles of the applications for the implementation of the said transitional provisions was published on the website of our institution and on the ÜTS portal on 3.4.2023 and came into effect.
In this context, the relevant application has been assessed under the "Notice on the implementation of the provisions of Regulation (EU) No 2023/607 No 2023/KK-1" and it has been considered appropriate to extend the validity period of the EC certificates with numbers 1783-MDD-079, 1783-MDD-080 until 31.12.2027 and the validity period of the EC certificates with numbers 1783-MDD-081, 1783-MDD-082 until 31.12.2028. In this regard, I request you to submit an application for registration/update of a document in ÜTS under our notice entitled "Notice on the implementation of the provisions of Regulation (EU) No 2023/607 No 2023/KK-2" and attach this response letter and its annexes to the relevant application;
I ask for your information and Support.

Dr. Mehmet Hakan FIRAT
Head of the Institution
Vice President of the Institution

ANNEX:
1-EK-1 (2 pages)
2-EK-2 (4 pages)
3-TSE Declaration (53 pages)
4-MDD Product List (87 pages)

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e-Mail: halkla.iliskiler@titck.gov.tr Website: https://www.titck.gov.tr Kep Address: titck@hs01.kep.tr

DENİZ YÜKSEL
NOTER YEMİNLİ TERCÜMAN
ADRES:
ATAKENT MAH. 223. SOK.
GÜNEŞPARK EVLERİ, 23H/2
KÜÇÜKÇEKMECE - İSTANBUL
Telefon: +90 544 901 82 83

I declare that I have translated this document, which was given to me for translation in the original, true to original, completely and correctly.
Sworn translator: Deniz Yüksel

Tercüme edilmek üzere bana verilen belgeyi aslına uygun, tam ve doğru tercüme ettiğimi beyan ederim
Noter Yeminli Tercüman: Deniz Yüksel

T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

Sayı : E-61749811-511.99-1126751 05.06.2023
Konu : 2023-KK-1

MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE TİC. LTD. ŞTİ.
İkitelli O.S.B. Demirciler San. Sitesi B7 Blok No:157 34306 Başakşehir / İSTANBUL

İlgi : 22.05.2023 tarihli, E-48535386-511.01.99-2379338 sayılı yazınız.

İlgi yazıda yer alan ve 1783-MDD-079, 1783-MDD-080, 1783-MDD-081 ve 1783-MDD-082 numaralı EC sertifikalarının belge geçerlilik süresinin uzatılması talebinizle ilgili olan başvurunuz incelenmiştir.

Avrupa Komisyonu'nun tıbbi cihazların tedarik edilememe riskini azaltmak amacıyla "*(AB) 2017/745 sayılı ve (AB) 2017/746 sayılı Tüzükleri belirli tıbbi cihazların ve in vitro tanı amaçlı tıbbi cihazların geçiş hükümlerini tadil eden (AB) 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü*" 20 Mart 2023 tarihinden itibaren yürürlüğe girecek şekilde 20 Mart 2023 tarihinde AB Resmi Gazetesinde yayımlanmıştır.

AB'nin güncel tıbbi cihaz mevzuatına uyum çalışmaları kapsamında; *(AB) 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü'ne* paralel olarak, "*Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmelik*" ve "*İn Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmelik*" adlı Yönetmeliklerimiz 2/4/2023 tarihli Resmi Gazete 'de yayımlanmış olup, *Tıbbi Cihaz Yönetmeliği* ve *İn Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde* söz konusu değişikler yapılmıştır.

Bu kapsamda, söz konusu geçiş hükümlerinin uygulanmasına yönelik başvuruların usul ve esaslarının açıklandığı "*2023/KK-1 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasında Dair Duyuru*" adlı Duyurumuz 3/4/2023 tarihinde Kurumumuz web sitesinde ve ÜTS Portal'da yayımlanarak yürürlüğe girmiştir.

Bu minvalde ilgili başvuru "*2023/KK-1 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru*" kapsamında değerlendirilmiş olup, başvurudaki *1783-MDD-079, 1783-MDD-080, numaralı EC Sertifikalarının* geçerlilik süresinin **31/12/2027** tarihine kadar, *1783-MDD-081, 1783-MDD-082 numaralı EC Sertifikalarının* geçerlilik süresinin **31/12/2028** tarihine kadar uzatılması uygun görülmüştür. Bu bağlamda, "***2023/KK-2 Sayılı*** (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru" adlı Duyurumuz kapsamında ÜTS'de belge kayıt/güncelleme başvurusu yapılması ve ilgili başvuruya bu cevabi yazımız ve eklerinin de eklenmesi hususunda;

Bilgilerinizi ve gereğini rica ederim.

Dr. Mehmet Hakan FIRAT
Kurum Başkanı a.
Kurum Başkan Yardımcısı

EK:
1-EK-1 (2 sayfa)
2-EK-2 (4 sayfa)
3-TSE Beyan (53 sayfa)
4-MDD Ürün Listesi (87 sayfa)

GLOBAL TERCÜME İSTANBUL NOTER YEMİNLİ TERCÜMAN

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Söğütözü Mahallesi, 2176.Sokak No:5 06520 Çankaya/ANKARA
Telefon No: (0 312) 218 30 00 Faks No: (0 312) 218 34 60
e-Posta: halkla.iliskiler@titck.gov.tr İnternet Adresi: https://www.titck.gov.tr
Kep Adresi: titck@hs01.kep.tr

GTİ GLOBAL TERCÜME İSTANBUL
DENİZ YÜKSEL NOTER YEMİNLİ TERCÜMAN
ADRES: ATAKENT MAH. 223. SOK. GÜNEŞPARK EVLERİ, 23H/2 KÜÇÜKÇEKMECE - İSTANBUL
Telefon: +90 544 901 82 83

MEDİKOKİM TIBBİ KİMYEVİ SAN.TİC.LTD.ŞTİ.
Demirciler Sanayi Sitesi B/7 Blok No:157
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info@medikokim.com
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DECLARATION OF CONFORMITY

Firm Name: MEDİKOKİM TIBBİ VE KİMYEVİ MALZEME SAN. VE TİC. LTD. ŞTİ.
Head Office Address: İKİTELLİ O.S.B. DEMİRCİLER SAN. SİTESİ B7 BLOK NO:157 BAŞAKŞEHİR 34306 –İSTANBUL TÜRKİYE
Production and Storage Address: İKİTELLİ O.S.B. ESKİ TURGUT ÖZAL BULVARI MEHMET ÇAKICI İŞ MERKEZİ NO:17/701 BAŞAKŞEHİR / İSTANBUL

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Web: www.medikokim.com **E-posta:** info@medikokim.com

Products: Fixation, Protection and Supporting Bands

No	Product Name	Brand Name	Model Name	GMDN Code
1	Adult Wrist Fixation Band	FESTERMED	ALH 2001	12102
2	Adult Ankle Fixation Band	FESTERMED	ALH 2002	12094
3	Adult Wrist and Ankle Fixation Band	FESTERMED	ALH 2004	12094
4	Adult Leg Fixation Band	FESTERMED	ALH 2003	12094
5	Adult Wrist and Ankle Fixation Band	FESTERMED	ALH 2006	12102-12094
6	Adult Wrist and Ankle Fixation Band	FESTERMED	ALH 2007	12102-12094
7	Adult Wrist Fixation Band - Dual	FESTERMED	TC 2009	12102
8	Adult Wrist and Ankle Fixation Band	FESTERMED	ALH 2011	12102-12094
9	Adult Wrist and Ankle Fixation Band	FESTERMED	ALH 2012	12102-12094
10	Ear Pad Support Band	DECKELMED	EPH 7001	41232
11	Ear Pad Support Band	DECKELMED	EPH 7002	41232
12	Wrist Support Band	FİXERBOARD	LHC01	12102
13	Wrist Support Band	FİXERBOARD	LHC02	12102
14	Wrist Support Band	FİXERBOARD	LHC03	12102
15	Wrist Support Band	FİXERBOARD	LHC04	12102
16	Wrist Support Band	FİXERBOARD	LHC05	12102
17	Wrist Support Band	FİXERBOARD	LHC06	12102

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18	Wrist Support Band	FİXERBOARD	LHB01	12102
19	Wrist Support Band	FİXERBOARD	LHB02	12102
20	Wrist Support Band	FİXERBOARD	LHB03	12102
21	Nasal Cannula Fixation Band	NASOMED	NTH 5001	36053
22	Nasal Cannula Fixation Band	NASOMED	NTH 5002	36053
23	Nasal Cannula Fixation Band	NASOMED	NTH 5001 TP	36053
24	Phototerapy Eye Band	SCHÜTZERMED	PEB 301	30881
25	Phototerapy Eye Band	SCHÜTZERMED	PEB 302	30881
26	Phototerapy Eye Band	SCHÜTZERMED	PEB 303	30881
27	Phototerapy Eye Band	SCHÜTZERMED	PEB STC 301	30881
28	Phototerapy Eye Band	SCHÜTZERMED	PEB STC 302	30881
29	Phototerapy Eye Band	SCHÜTZERMED	PEB STC 303	30881
30	Phototerapy Eye Band	SCHÜTZERMED	PEB YT 301	30881
31	Phototerapy Eye Band	SCHÜTZERMED	PEB YT 302	30881
32	Phototerapy Eye Band	SCHÜTZERMED	PEB YT 303	30881
33	Phototerapy Eye Band	SCHÜTZERMED	PEB TPD 301	30881
34	Endotracheal Cannula Fixation Band	STAENDERMED	ETHCLPTP	35815
35	Endotracheal Cannula Fixation Band	STAENDERMED	ETH CLPM101	35815
36	Endotracheal Cannula Fixation Band	STAENDERMED	ETH CLPM102	35815
37	Endotracheal Cannula Fixation Band	STAENDERMED	ETH SC 101	35815
38	Endotracheal Cannula Fixation Band	STAENDERMED	ETH SCTP	35815
39	Endotracheal Cannula Fixation Band	STAENDERMED	ETH SC 102	35815
40	Endotracheal Cannula Fixation Band	STAENDERMED	ETH SCM201	35815
41	Endotracheal Cannula Fixation Band	STAENDERMED	ETH SCM202	35815
42	Endotracheal Cannula Fixation Band	STAENDERMED	ETH SCM203	35815
43	Endotracheal Cannula Fixation Band	STAENDERMED	ETH VM101	35815
44	Endotracheal Cannula Fixation Band	STAENDERMED	ETH VM102	35815
45	Endotracheal Cannula Fixation Band	STAENDERMED	ETH 201	35815
46	Endotracheal Cannula Fixation Band	STAENDERMED	ETH 202	35815
47	Endotracheal Cannula Fixation Band	STAENDERMED	ETH 203	35815
48	Endotracheal Cannula	STAENDERMED	ETH TP	35815

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	Fixation Band			
49	Nasal Tampon Support Band	STOPPERMED	NTH 01	36053
50	Tracheal Cannula Fixation Band	TRAEGERMED	TCHS01	35752
51	Tracheal Cannula Fixation Band	TRAEGERMED	TCHS02	35752
52	Tracheal Cannula Fixation Band	TRAEGERMED	TCHS03	35752
53	Tracheal Cannula Fixation Band	TRAEGERMED	TCH R 01	35752
54	Tracheal Cannula Fixation Band	TRAEGERMED	TCH R 02	35752
55	Tracheal Cannula Fixation Band	TRAEGERMED	TCH R 03	35752
56	Tracheal Cannula Fixation Band	TRAEGERMED	TCHSTP	35752
57	Tracheal Cannula Fixation Band	TRAEGERMED	TCH R TP	35752
58	Adult Wrist Fixation Band	TSM	TSM UYESB 2001	12102
59	Adult Ankle Fixation Band	TSM	TSM UYASB 2002	12094
60	Adult Wrist Fixation Band	TSM	TSM YESB 2001	12102
61	Adult Ankle Fixation Band	TSM	TSM YASB 2002	12094
62	Adult Leg Fixation Band	TSM	TSM YBSB 2003	12102-12094
63	Baby Wrist and Ankle Fixation Band	TSM	TSM UBEASB 3001	12102-12094
64	Phototerapy Eye Band	TSM	TSM 301	30881
65	Phototerapy Eye Band	TSM	TSM 302	30881
66	Phototerapy Eye Band	TSM	TSM 303	30881
67	Endotracheal Cannula Fixation Band	TSM	TSM ETT 102	35815
68	Endotracheal Cannula Fixation Band	TSM	TSM ETT 101	35815
69	Tracheal Cannula Fixation Band	TSM	TSM TKT 01	35752
70	Tracheal Cannula Fixation Band	TSM	TSM 01 TP	35752
71	Tracheal Cannula Fixation Band	TSM	TSM 02 TP	35752
72	Tracheal Cannula Fixation Band	TSM	TSM 03 TP	35752

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Classification: 93/42/AT Annex IX Rule 1, Class I Sterile

Conformity Assessment: Annex V

ISO 13485:2016	**EN ISO 9001:2015**	**EN ISO 11137-1/A2:2019**
EN ISO 14971:2019	**EN ISO 10993-1:2020**	**EN ISO 11137-2:2015**
EN ISO 20417:2021	**EN ISO 10993-4:2017**	**EN ISO 11607-1:2020**
EN ISO 15223-1: 2021	**EN ISO 10993-5: 2009**	**EN ISO 11607-2:2020**
EN 556-1:2001/AC:2006	**EN ISO 10993-10:2014**	**EN ISO 11737-1:2018**
EN ISO 29073-1:1992	**EN ISO 10993-11: 2018**	**EN ISO 11737-2: 2020**
EN ISO 29073-3:1992	**EN ISO 9073-2:1996**	**EN 1644-1:1997**
EN 17141:2020	**EN ISO 14644 -1:2015**	**EN ISO 9073-4:2021**
ISO 9092:2019	**EN ISO 14644 -2:2015**	**DIN 53923**
ASTM F 1980:2007(2011)	**EN ISO 14644-3:2019**	**ASTM F 1929:1998**
Meddev 2.4/1 rev.9(2010)	**ISO 14644 -4:2001**	**Meddev 2.12/1 rev.8(2013)**
Meddev 2.7/1 rev.4(2016)	**ISO 14644 -5:2004**	**(Ph. Eur.) 9th Edition**
ASTM-F 1886:2016	**Meddev 2.12/2 rev.2(2012)**	

- We here with declare that the manufacturing of the products meet the provisions of 93/42/AT Medical Device Regulations with its 2007/47/AT changes along with basic requirements and standards listed above.

  We also hereby declare that our products are;
- • It does not contain a Combination of Pharmaceuticals and Medical Devices as stated in Article 1 of the **726/2004** regulation;
- • It does not Contain Human Blood as stated in Annex I section 7.4 of the 93/42 EEC regulation added by the **2000/70/EC** Regulation of the European Parliament and the Council, and
- • Does not contain Animal Origin as specified in regulation **722/2012 EC** and **2003/32/EC** of the European Parliament and Council.

We declare that it is supplied to the market and that all responsibility lies with the manufacturer.

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Notified Body:	Turkish Standards Institution (TSE)
Notified Body Address:	Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA/TÜRKİYE
Notified Body Numbers:	1783
Number	
Certificate of Full Quality Assurance:	1783-MDD-082 /rev03
Valid Until:	27.02.2023
Certificate Issue Date:	27.02.2018
Declaration Place:	İstanbul
Declaration Date:	04.10.2022

Muhammed PEZÜK

General Manager