

	Declaration Of Conformity	Document No	TF.01.02
		Revision No	02
		Revision Date	16.07.2024
		Issue Date	18.10.2022
		Page	

Legal Manufacturer Name	BIOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SAN.VE TİC A.Ş
SRN Number	TR-MF-000023145
Legal Manufacturer Address	İslampaşa Mh. 2 Nolu Şehitler Cd. No:41/G MERKEZ RİZE
Risk Class	Class IS
Rule	Rule I
Conformity Assessment Route	Annex IX - Parts I and II - Conformity assessment based on the Quality management system and on assessment of the technical documentation
Trade Name	Biotex
Device Name	Sterile Disposable Surgical Drapes, Gowns and Sets
Basic UDI-DI	8681881208TD01HS, 868181208GA1N8, 868181208KK1PS, 868181208CS1PA, 868181208MK1Q4, 868181208PS1RB, 868181208SS1RS, 868181208T1YP
Notified Body	Kiwa Belgelendirme Hizmetleri A.Ş ITOSB 9. STREET NO:15 Tuzla-İstanbul
EC Certificate No	
Certificate Revision No and Issue Date	16.07.2024 Rev:02
Certificate Expiration Date	27.05.2024
End date of extended validity/transition period	31.12.2028

BIOTEX MEDİKAL TEKSTİL İTH.
 İHR. SAN. VE TİC. A.Ş.
 Merkez : İslampaşa Mh. 2 Nolu Şehitler Cd.
 İslampaşa İş Merkezi No 41/G Merkez / Rize
 Tel: 0464 213 15 38 Fax: 0464 213 16 38
 Etiler Aksoy Cad. No: 3 nolu Cad.no:14
 Rize / Aksoy Mh. 3 nolu Cad. No: 14
 Yeşilçay V.D.: 0464 300 01 01
 Mersis No: 70041552100001

	Declaration Of Conformity	Document No	TF.01.02
		Revision No	02
		Revision Date	16.07.2024
		Issue Date	18.10.2022
		Page	

This EU declaration of conformity is issued under the sole responsibility of the legal manufacturer.

The device that is covered by the present declaration is in conformity with this 2017/745 Medical Device Regulation.

The device list and UDI-DI code list are defined in the list with document code TF.01.02.01.

The device description is presented as an additional document together with the declaration of conformity.

LIST OF PRODUCTS:

UBB	UDI-DI CODE	PRODUCTION NAME (ÜRÜN ADI)	PRODUCTION CODE (ÜRÜN KOD)	EMDN	BASIC-UDI-DI
8681812081078	08681812081078	ABDOMINAL DRAPE (ABDOMİNAL ÖRTÜ)	RMD-327-1	T020102	868181208GA1N8
8681812080309	08681812080309	ABDOMINAL DRAPE KIT (ABDOMİNAL ÖRTÜ SETİ)	RMD-327	T0202	868181208TD01HS
8681812080583	08681812080583	TOOL TABLE DRAPE (ALET MASA ÖRTÜSÜ)	RMD-364	T020102	868181208GA1N8
8681812081306	08681812081306	ANESTHESIA DRAPE (ANESTEZİ ÖRTÜSÜ)	BİO-AÖ100	T020102	868181208GA1N8
8681812080514	08681812080514	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310	T0202	868181208TD01HS
8681812080842	08681812080842	ANGIOGRAPHY DRAPE (ANJİO ÖRTÜSÜ)	RMD-310-1	T020102	868181208GA1N8
8681812080323	08681812080323	ARTHROSCOPY DRAPE KIT (ARTROSKOPİ ÖRTÜ SETİ)	RMD-314	T0202	868181208TD01HS
8681812080149	08681812080149	ARTHROSCOPY DRAPE (ARTROSKOPİ ÖRTÜSÜ)	RMD-314-1	T020102	868181208GA1N8

BIOTEX MEDİKAL TEKSTİL İTH.
İHR. SAN. VE TİC. A.Ş.
Markaz : İslanbul Mah. 2 Nolu Şahiller Cad.
İlac Nolu İş Merkezi No 41/G Merkez / Rize
Tel: 0464 213 16 38 Fax: 0464 213 16 38
Telex: 464 213 16 38 Fax: 0464 213 16 38
Kale: Aksoy Mah. 3 Nolu Cad. No: 14
Kaleendere Mah. 521 Tel: 0464 300 01 01
Yedigöller V.D. : 521 Tic. Sic. No: 8456
Yedigöller V.D. : 521 Tic. Sic. No: 8456
Yedigöller V.D. : 521 Tic. Sic. No: 8456

Declaration Of Conformity



Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812080675	08681812080675	EMBRYO TRANSFER (E.T.) KIT (EMBRİYO TRANSFER (ET) SETİ)	RMD-365	T0202	868181208TD01HS
8681812080040	08681812080040	GENERAL SURGERY DRAPE KIT (GENEL CERRAHİ ÖRTÜ SETİ)	RMD-326	T0202	868181208TD01HS
8681812080873	08681812080873	EYE DRAPE KIT (GÖZ ÖRTÜ SETİ)	RMD-340	T0202	868181208TD01HS
8681812080934	08681812080934	EYE DRAPE (GÖZ ÖRTÜSÜ)	RMD-340-1	T020102	868181208GA1N8
8681812081399	08681812081399	HYSTEROSCOPY DRAPE KIT (HİSTEROSKOPİ ÖRTÜ SETİ)	BİO-HÖ100	T0202	868181208TD01HS
8681812080170	08681812080170	I.V.F. DRAPE (I.V.F. ÖRTÜSÜ)	RMD-322-1	T020102	868181208GA1N8
8681812080682	08681812080682	I.V.F. DRAPE KIT (TÜP BEBEK ÖRTÜ SETİ)	RMD-322	T0202	868181208TD01HS
8681812080224	08681812080224	IMPLANT DRAPE KIT (İMLANT ÖRTÜ SETİ)	RMD-342	T0202	868181208TD01HS
8681812080446	08681812080446	HIP U DRAPE (KALÇA U ÖRTÜSÜ)	RMD-318-1	T020102	868181208GA1N8
8681812080033	08681812080033	HEART VALVE REPLACEMENT DRAPE KIT(KALP KAPAKÇIĞI DEĞİŞİM ÖRTÜ SETİ)	RMD-312	T0202	868181208TD01HS
8681812081283	08681812081283	CAMERA CASE (KAMERA KILIFI)	BİO-KK 100	T030202	868181208KK1PS
8681812080927	08681812080927	CARDIOVASCULAR DRAPE KIT (KARDİYOVASKÜLER ÖRTÜ SETİ)	RMD-313	T0202	868181208TD01HS
8681812080248	08681812080248	E.N.T. DRAPE KIT (K.B.B. ÖRTÜ SETİ)	RMD-320	T0202	868181208TD01HS
8681812080064	08681812080064	CHEMOTHERAPY GOWN L (KEMOTERAPİ ÖNLÜĞÜ L)	SRCÖ-44MUMS-125	T020499	868181208CS1PA
8681812080392	08681812080392	CHEMOTHERAPY GOWN M (KEMOTERAPİ ÖNLÜĞÜ M)	SRCÖ-44MUMS-125	T020499	868181208CS1PA
8681812080620	08681812080620	CHEMOTHERAPY GOWN S (KEMOTERAPİ ÖNLÜĞÜ S)	SRCÖ-44MUMS-125	T020499	868181208CS1PA
8681812080156	08681812080156	CHEMOTHERAPY GOWN XL (KEMOTERAPİ ÖNLÜĞÜ XL)	SRCÖ-44MUMS-125	T020499	868181208CS1PA



Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812080651	08681812080651	CHEMOTHERAPY DRAPE KIT (KEMOTERAPİ ÖRTÜ SETİ)	RMD-345	T0202	868181208TD01HS
8681812080484	08681812080484	CHEMOTHERAPY DRAPE (KEMOTERAPİ ÖRTÜSÜ)	RMD-345-1	T020102	868181208GA1N8
8681812080088	08681812080088	CRANIOTOMY DRAPE KIT (KRANIOTOMİ ÖRTÜ SETİ)	RMD-332	T0202	868181208TD01HS
8681812081214	08681812081214	SMALL SURGERY PACKET KIT (KÜÇÜK AMELİYAT BOHÇA SETİ)	RMD-326K	T0202	868181208TD01HS
8681812081351	08681812081351	ABORTION DRAPE KIT (KÜRTAJ ÖRTÜ SETİ)	BİO-KÖ100	T0202	868181208TD01HS
8681812080422	08681812080422	K.V.C. DRAPE (K.V.C. ÖRTÜSÜ)	RMD-313-1	T020102	868181208GA1N8
8681812081368	08681812081368	LAMINECTOMY DRAPE KIT (LAMİNEKTOMİ ÖRTÜ SETİ)	BİO-LMÖ100	T0202	868181208TD01HS
8681812080897	08681812080897	LAPAROTOMY DRAPE KIT (LAPAROTOMİ ÖRTÜ SETİ)	RMD-328	T0202	868181208TD01HS
8681812080958	08681812080958	LAPAROTOMY DRAPE (LAPAROTOMİ ÖRTÜSÜ)	RMD-328-1	T020102	868181208GA1N8
8681812080781	08681812080781	LAPAROSCOPY DRAPE KIT (LAPAROSKOPİ ÖRTÜ SETİ)	RMD-329	T0202	868181208TD01HS
8681812080293	08681812080293	LAPAROSCOPY DRAPE (LAPAROSKOPİ ÖRTÜSÜ)	RMD-329-1	T020102	868181208GA1N8
8681812080743	08681812080743	LASER EYE DRAPE KIT (LAZER GÖZ ÖRTÜ SETİ)	RMD-337	T0202	868181208TD01HS
8681812081337	08681812081337	LITHOTOMY DRAPE KIT (LİTOTOMİ ÖRTÜ SETİ)	BİO-LÖS100	T0202	868181208TD01HS
8681812081320	08681812081320	L DRAPE (L ÖRTÜSÜ)	BİO-LÖ100	T020102	868181208GA1N8
8681812081092	08681812081092	MAJOR SURGERY DRAPE KIT (MAJÖR CERRAHİ ÖRTÜ SETİ)	RMD-375	T0202	868181208TD01HS
8681812080057	08681812080057	SWIMSUIT TABLE CLOTH (MAYO MASA ÖRTÜSÜ)	RMD-MM100	T020102	868181208GA1N8

Declaration Of Conformity



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812081054	08681812081054	STERIL ANGIOGRAPHY KIT PANELED FEMORAL - H.P. (STERİL ANGİO SETİ PANELLİ FEMORAL- H.P.)	RMD-372	T0202	868181208TD01HS
8681812080330	08681812080330	STERIL BRAIN SURGERY KIT (STERİL BEYİN CERRAHİ SETİ)	RMD-348	T0202	868181208TD01HS
8681812080590	08681812080590	STERIL PACKET KIT (STERİL BOHÇA SETİ)	RMD-365	T0202	868181208TD01HS
8681812080774	08681812080774	STERIL GYNECOLOGY - CYSTOSCOPY KIT - H.P. (STERİL JİNEKOLOJİ-SİSTOSKOPİ SETİ - H.P.)	RMD-367	T0202	868181208TD01HS
8681812080477	08681812080477	STERIL NON-POSH ARTHROSCOPY KIT (STERİL POŞSUZ ARTROSKOPİ SETİ)	RMD-371	T0202	868181208TD01HS
8681812081269	08681812081269	STERIL FULL CONSOLIDATED SURGERY GOWN (STERİL TAM TAKVİYELİ CERRAHİ ÖNLÜK)	SRCÖ- 55MUMTT- 125	T020499	868181208CS1PA
8681812081276	08681812081276	STERIL FULL CONSOLIDATED SURGERY GOWN (STERİL TAM TAKVİYELİ CERRAHİ ÖNLÜK)	SRCÖ- 55BUMTT-125	T020499	868181208CS1PA
8681812080385	08681812080385	CONSOLIDATED SURGERY GOWN L (TAKVİYELİ CERRAHİ ÖNLÜK L)	SRCÖ- 35MUMT-125	T020402	868181208T1YP
8681812080903	08681812080903	CONSOLIDATED SURGERY GOWN M (TAKVİYELİ CERRAHİ ÖNLÜK M)	SRCÖ- 35MUMT-125	T020402	868181208T1YP
8681812080354	08681812080354	CONSOLIDATED SURGERY GOWN S (TAKVİYELİ CERRAHİ ÖNLÜK S)	SRCÖ- 35MUMT-125	T020402	868181208T1YP
8681812080569	08681812080569	CONSOLIDATED SURGERY GOWN XL (TAKVİYELİ CERRAHİ ÖNLÜK XL)	SRCÖ- 35MUMT-125	T020402	868181208T1YP
8681812080965	08681812080965	FULL CONSOLIDATED SURGERY GOWN L (TAM TAKVİYELİ CERRAHİ ÖNLÜK L)	SRCÖ- 35MUMTT- 125	T020499	868181208CS1PA
8681812080378	08681812080378	FULL CONSOLIDATED SURGERY	SRCÖ-	T020499	868181208CS1PA

Declaration Of Conformity



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812081863	08681812081863	ANGIOGRAPHY DRAPE KIT - 10 (ANJIOGRAFI ÖRTÜ SETİ-10)	RMD-310-10	T0202	868181208TD01HS
8681812081870	08681812081870	ANGIOGRAPHY DRAPE KIT -11 (ANJIOGRAFI ÖRTÜ SETİ-11)	RMD-310-11	T0202	868181208TD01HS
8681812081887	08681812081887	ANGIOGRAPHY DRAPE KIT -12 (ANJIOGRAFI ÖRTÜ SETİ-12)	RMD-310-12	T0202	868181208TD01HS
8681812081894	08681812081894	ANGIOGRAPHY DRAPE KIT -13 (ANJIOGRAFI ÖRTÜ SETİ-13)	RMD-310-13	T0202	868181208TD01HS
8681812081900	08681812081900	ANGIOGRAPHY DRAPE KIT -14 (ANJIOGRAFI ÖRTÜ SETİ-14)	RMD-310-14	T0202	868181208TD01HS
8681812081917	08681812081917	ANGIOGRAPHY DRAPE KIT -15 (ANJIOGRAFI ÖRTÜ SETİ-15)	RMD-310-15	T0202	868181208TD01HS
8681812081924	08681812081924	ARTHROSCOPY DRAPE KIT -2 (ARTROSKOPİ ÖRTÜ SETİ-2)	RMD-314-2	T0202	868181208TD01HS
8681812081931	08681812081931	ARTHROSCOPY DRAPE KIT -3 (ARTROSKOPİ ÖRTÜ SETİ-3)	RMD-314-3	T0202	868181208TD01HS
8681812081948	08681812081948	ARTHROSCOPY DRAPE KIT -4 (ARTROSKOPİ ÖRTÜ SETİ-4)	RMD-314-4	T0202	868181208TD01HS
8681812081955	08681812081955	ARTHROSCOPY DRAPE KIT -5 (ARTROSKOPİ ÖRTÜ SETİ-5)	RMD-314-5	T0202	868181208TD01HS
8681812081962	08681812081962	ARTHROSCOPY DRAPE KIT -6 (ARTROSKOPİ ÖRTÜ SETİ-6)	RMD-314-6	T0202	868181208TD01HS
8681812081979	08681812081979	ARTHROSCOPY DRAPE KIT -7 (ARTROSKOPİ ÖRTÜ SETİ-7)	RMD-314-7	T0202	868181208TD01HS
8681812081986	08681812081986	ARTHROSCOPY DRAPE KIT -8 (ARTROSKOPİ ÖRTÜ SETİ-8)	RMD-314-8	T0202	868181208TD01HS
8681812081993	08681812081993	ARTHROSCOPY DRAPE KIT -9 (ARTROSKOPİ ÖRTÜ SETİ-9)	RMD-314-9	T0202	868181208TD01HS
8681812082006	08681812082006	ARTHROSCOPY DRAPE KIT -10 (ARTROSKOPİ ÖRTÜ SETİ-10)	RMD-314-10	T0202	868181208TD01HS



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812082013	08681812082013	ARTHROSCOPY DRAPE KIT -11 (ARTROSKOPİ ÖRTÜ SETİ-11)	RMD-314-11	T0202	868181208TD01HS
8681812082020	08681812082020	ARTHROSCOPY DRAPE KIT -12 (ARTROSKOPİ ÖRTÜ SETİ-12)	RMD-314-12	T0202	868181208TD01HS
8681812082037	08681812082037	ARTHROSCOPY DRAPE KIT -13 (ARTROSKOPİ ÖRTÜ SETİ-13)	RMD-314-13	T0202	868181208TD01HS
8681812082044	08681812082044	ARTHROSCOPY DRAPE KIT -14 (ARTROSKOPİ ÖRTÜ SETİ-14)	RMD-314-14	T0202	868181208TD01HS
8681812082051	08681812082051	ARTHROSCOPY DRAPE KIT 15(ARTROSKOPİ ÖRTÜ SETİ-15)	RMD-314-15	T0202	868181208TD01HS
8681812082068	08681812082068	ARTHROSCOPY DRAPE -2 (ARTROSKOPİ ÖRTÜSÜ -2)	RMD-318-16	T020102	868181208GA1N8
8681812082075	08681812082075	ARTHROSCOPY DRAPE -3 (ARTROSKOPİ ÖRTÜSÜ -3)	RMD-318-17	T020102	868181208GA1N8
8681812082082	08681812082082	ARTHROPLASTY (HIP) DRAPE KIT -2 (ATROPLASTİ (KALÇA) ÖRTÜ SETİ- 2)	RMD-318-2	T0202	868181208TD01HS
8681812082099	08681812082099	ARTHROPLASTY (HIP) DRAPE KIT -3 (ATROPLASTİ (KALÇA) ÖRTÜ SETİ- 3)	RMD-318-3	T0202	868181208TD01HS
8681812082105	08681812082105	BANDED FOOT DRAPE -2 (BANTLI AYAK ÖRTÜSÜ -2)	RMD- BAÖ100-2	T020102	868181208GA1N8
8681812082112	08681812082112	BANDED FOOT DRAPE -3 (BANTLI AYAK ÖRTÜSÜ -3)	RMD- BAÖ100-3	T020102	868181208GA1N8
8681812082129	08681812082129	BANDED FOOT DRAPE -4 (BANTLI AYAK ÖRTÜSÜ -4)	RMD- BAÖ100-4	T020102	868181208GA1N8
8681812082136	08681812082136	BANDED FOOT DRAPE -5 (BANTLI AYAK ÖRTÜSÜ -5)	RMD- BAÖ100-5	T020102	868181208GA1N8
8681812082143	08681812082143	BANDED FOOT -2 (BANTLI ÖRTÜ-2)	BiO-BÖ100-2	T020102	868181208GA1N8
8681812082150	08681812082150	BANDED FOOT -3 (BANTLI ÖRTÜ-3)	BiO-BÖ100-3	T020102	868181208GA1N8



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812082167	08681812082167	BANDED FOOT -4 (BANTLI ÖRTÜ-4)	BiO-BÖ100-4	T020102	868181208GA1N8
8681812082174	08681812082174	BANDED FOOT -5 (BANTLI ÖRTÜ-5)	BiO-BÖ100-5	T020102	868181208GA1N8
8681812082181	08681812082181	BANDED FOOT -6 (BANTLI ÖRTÜ-6)	BiO-BÖ100-6	T020102	868181208GA1N8
8681812082198	08681812082198	BANDED FOOT -7 (BANTLI ÖRTÜ-7)	BiO-BÖ100-7	T020102	868181208GA1N8
8681812082204	08681812082204	BANDED FOOT -8 (BANTLI ÖRTÜ-8)	BiO-BÖ100-8	T020102	868181208GA1N8
8681812082211	08681812082211	BANDED FOOT -9 (BANTLI ÖRTÜ-9)	BiO-BÖ100-9	T020102	868181208GA1N8
8681812082228	08681812082228	BANDED FOOT -10 (BANTLI ÖRTÜ-10)	BiO-BÖ100-10	T020102	868181208GA1N8
8681812082235	08681812082235	BY-PASS DRAPE KIT -2 (BY-PASS ÖRTÜ SETİ-2)	RMD-311-2	T0202	868181208TD01HS
8681812082242	08681812082242	BY-PASS DRAPE KIT -3 (BY-PASS ÖRTÜ SETİ-3)	RMD-311-3	T0202	868181208TD01HS
8681812082259	08681812082259	BY-PASS DRAPE KIT -4 (BY-PASS ÖRTÜ SETİ-4)	RMD-311-4	T0202	868181208TD01HS
8681812082266	08681812082266	BY-PASS DRAPE KIT -5 (BY-PASS ÖRTÜ SETİ-5)	RMD-311-5	T0202	868181208TD01HS
8681812082273	08681812082273	BY-PASS DRAPE KIT -6 (BY-PASS ÖRTÜ SETİ-6)	RMD-311-6	T0202	868181208TD01HS
8681812082280	08681812082280	BY-PASS DRAPE KIT -7 (BY-PASS ÖRTÜ SETİ-7)	RMD-311-7	T0202	868181208TD01HS
8681812082297	08681812082297	BY-PASS DRAPE KIT -8 (BY-PASS ÖRTÜ SETİ-8)	RMD-311-8	T0202	868181208TD01HS
8681812082303	08681812082303	BY-PASS DRAPE KIT -9 (BY-PASS ÖRTÜ SETİ-9)	RMD-311-9	T0202	868181208TD01HS
8681812082310	08681812082310	BY-PASS DRAPE KIT -10 (BY-PASS ÖRTÜ SETİ-10)	RMD-311-10	T0202	868181208TD01HS
8681812082327	08681812082327	BY-PASS DRAPE KIT -11 (BY-PASS ÖRTÜ SETİ-11)	RMD-311-11	T0202	868181208TD01HS
8681812082334	08681812082334	BY-PASS DRAPE KIT -12 (BY-PASS ÖRTÜ SETİ-12)	RMD-311-12	T0202	868181208TD01HS



Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

		ÖRTÜ SETİ-12)			
8681812082341	08681812082341	BY-PASS DRAPE KIT -13 (BY-PASS ÖRTÜ SETİ-13)	RMD-311-13	T0202	868181208TD01HS
8681812082358	08681812082358	BY-PASS DRAPE KIT -14 (BY-PASS ÖRTÜ SETİ-14)	RMD-311-14	T0202	868181208TD01HS
8681812082365	08681812082365	SURGERY GOWN KIT-2 (CERRAHİ ÖNLÜK SETİ-2)	RMD-349-1	T0202	868181208TD01HS
8681812082372	08681812082372	SURGERY GOWN KIT-3 (CERRAHİ ÖNLÜK SETİ-3)	RMD-349-2	T0202	868181208TD01HS
8681812082389	08681812082389	DRAPE KIT -2 (ÖRTÜ SETİ -2)	COVER-2	T0202	868181208TD01HS
8681812082396	08681812082396	DRAPE KIT -3 (ÖRTÜ SETİ -3)	COVER-3	T0202	868181208TD01HS
8681812082402	08681812082402	DOUBLE POSH EYE DRAPES -2 (ÇİFT POŞLU GÖZ ÖRTÜLERİ-2)	RMD-339-2	T020102	868181208GA1N8
8681812082419	08681812082419	DOUBLE POSH EYE DRAPES -3 (ÇİFT POŞLU GÖZ ÖRTÜLERİ-3)	RMD-339-3	T020102	868181208GA1N8
8681812082426	08681812082426	DOUBLE POSH EYE DRAPES -4 (ÇİFT POŞLU GÖZ ÖRTÜLERİ-4)	RMD-339-4	T020102	868181208GA1N8
8681812082433	08681812082433	DOUBLE POSH EYE DRAPES -5 (ÇİFT POŞLU GÖZ ÖRTÜLERİ-5)	RMD-339-5	T020102	868181208GA1N8
8681812082440	08681812082440	PERFORATED TAPE DRAPE -2 (DELİKLİ BANTLI ÖRTÜ -2)	RMD-DBÖ100-2	T020102	868181208GA1N8
8681812082457	08681812082457	PERFORATED TAPE DRAPE -3 (DELİKLİ BANTLI ÖRTÜ -3)	RMD-DBÖ100-3	T020102	868181208GA1N8
8681812082464	08681812082464	PERFORATED TAPE DRAPE -34(DELİKLİ BANTLI ÖRTÜ -4)	RMD-DBÖ100-4	T020102	868181208GA1N8
8681812082471	08681812082471	PERFORATED TAPE DRAPE -5(DELİKLİ BANTLI ÖRTÜ -5)	RMD-DBÖ100-5	T020102	868181208GA1N8
8681812082488	08681812082488	PERFORATED TAPE DRAPE -6 (DELİKLİ BANTLI ÖRTÜ -6)	RMD-DBÖ100-6	T020102	868181208GA1N8
8681812082495	08681812082495	PERFORATED TAPE DRAPE -7	RMD-	T020102	868181208GA1N8

Declaration Of Conformity



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

			7		
8681812082655	08681812082655	FLAT DRAPE -8 (DÜZ ÖRTÜ -8)	RMD-DÖ100-8	T020102	868181208GA1N8
8681812082662	08681812082662	FLAT DRAPE -9 (DÜZ ÖRTÜ -9)	RMD-DÖ100-9	T020102	868181208GA1N8
8681812082679	08681812082679	FLAT DRAPE -10 (DÜZ ÖRTÜ -10)	RMD-DÖ100-10	T020102	868181208GA1N8
8681812082686	08681812082686	LIMB DRAPE KIT -2 (EKSTREMİTE ÖRTÜ SETİ-2)	RMD-315-2	T0202	868181208TD01HS
8681812082693	08681812082693	LIMB DRAPE KIT -3 (EKSTREMİTE ÖRTÜ SETİ-3)	RMD-315-3	T0202	868181208TD01HS
8681812082709	08681812082709	LIMB DRAPE KIT -4 (EKSTREMİTE ÖRTÜ SETİ-4)	RMD-315-4	T0202	868181208TD01HS
8681812082716	08681812082716	LIMB DRAPE KIT -5 (EKSTREMİTE ÖRTÜ SETİ-5)	RMD-315-5	T0202	868181208TD01HS
8681812082723	08681812082723	LIMB DRAPE -2 (EKSTREMİTE ÖRTÜSÜ -2)	RMD-315-11	T020102	868181208GA1N8
8681812082730	08681812082730	LIMB DRAPE -3 (EKSTREMİTE ÖRTÜSÜ -3)	RMD-315-12	T020102	868181208GA1N8
8681812082747	08681812082747	EMBRYO TRANSFER (ET) KIT -2 (EMBRIYO TRANSFER (ET) SETİ-2)	RMD-365-2	T0202	868181208TD01HS
8681812082754	08681812082754	EMBRYO TRANSFER (ET) KIT -3 (EMBRIYO TRANSFER (ET) SETİ-3)	RMD-365-3	T0202	868181208TD01HS
8681812082761	08681812082761	GENERAL SURGERY DRAPE KIT -2 (GENEL CERRAHİ ÖRTÜ SETİ-2)	RMD-326-2	T0202	868181208TD01HS
8681812082778	08681812082778	GENERAL SURGERY DRAPE KIT -3 (GENEL CERRAHİ ÖRTÜ SETİ-3)	RMD-326-3	T0202	868181208TD01HS
8681812082785	08681812082785	GENERAL SURGERY DRAPE KIT -4 (GENEL CERRAHİ ÖRTÜ SETİ-4)	RMD-326-4	T0202	868181208TD01HS
8681812082792	08681812082792	GENERAL SURGERY DRAPE KIT -5	RMD-326-5	T0202	868181208TD01HS



TF.01.02

02

16.07.2024

18.10.2022

BIOTEX MEDİKAL TEKSTİL İTH.
İHR. SAN. VE TİC. A.Ş.
 Merkez : İstanbul Mah. 2 Nolu Şahitler Cad.
 İçişleri İş Merkezi No 4/1G Merkez / Rize
 Tel: 0464 213 16 38 Fax: 0464 213 16 38
 Tlx: 0464 213 16 38
 Etiler Akademi Mah. 3 Nolu Cad no: 14
 Rakkandere - Beşiktaş / İstanbul
 Tel: 0464 300 01 01
 Yesilcaý V.D. : 0464 5621 Tic. Sic. No: 8456
 Mersis No : 70041552100001



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812082952	08681812082952	EYE DRAPE -3 (GÖZ ÖRTÜSÜ -3)	RMD-340-7	T020102	868181208GA1N8
8681812082969	08681812082969	I.V.F. DRAPE KIT -2 (TÜP BEBEK ÖRTÜ SETİ-2)	RMD-322-2	T0202	868181208TD01HS
8681812082976	08681812082976	I.V.F. DRAPE KIT -3 (TÜP BEBEK ÖRTÜ SETİ-3)	RMD-322-3	T0202	868181208TD01HS
8681812082983	08681812082983	I.V.F. DRAPE KIT -4 (TÜP BEBEK ÖRTÜ SETİ-4)	RMD-322-4	T0202	868181208TD01HS
8681812082990	08681812082990	I.V.F. DRAPE KIT -5 (TÜP BEBEK ÖRTÜ SETİ-5)	RMD-322-5	T0202	868181208TD01HS
8681812083003	08681812083003	I.V.F. DRAPE -2 (TÜP BEBEK ÖRTÜSÜ -2)	RMD-322-6	T020102	868181208GA1N8
8681812083010	08681812083010	I.V.F. DRAPE -3 (TÜP BEBEK ÖRTÜSÜ -3)	RMD-322-7	T020102	868181208GA1N8
8681812083027	08681812083027	IMPLANT DRAPE KIT -2 (İMLANT ÖRTÜ SETİ-2)	RMD-342-2	T0202	868181208TD01HS
8681812083034	08681812083034	IMPLANT DRAPE KIT -3 (İMLANT ÖRTÜ SETİ-3)	RMD-342-3	T0202	868181208TD01HS
8681812083041	08681812083041	E.N.T. DRAPE KIT -2 (K.B.B. ÖRTÜ SETİ-2)	RMD-320-2	T0202	868181208TD01HS
8681812083058	08681812083058	E.N.T. DRAPE KIT -3 (K.B.B. ÖRTÜ SETİ-3)	RMD-320-3	T0202	868181208TD01HS
8681812083065	08681812083065	K.V.C. DRAPE -2 (K.V.C. ÖRTÜSÜ -2)	RMD-313-11	T020102	868181208GA1N8
8681812083072	08681812083072	K.V.C. DRAPE -3 (K.V.C. ÖRTÜSÜ -3)	RMD-313-12	T020102	868181208GA1N8
8681812083089	08681812083089	HIP U DRAPE (KALÇA U ÖRTÜSÜ)	RMD-318-11	T020102	868181208GA1N8
8681812083096	08681812083096	HIP U DRAPE (KALÇA U ÖRTÜSÜ)	RMD-318-12	T020102	868181208GA1N8
8681812083102	08681812083102	HIP U DRAPE (KALÇA U ÖRTÜSÜ)	RMD-318-13	T020102	868181208GA1N8
8681812083119	08681812083119	HIP U DRAPE (KALÇA U ÖRTÜSÜ)	RMD-318-14	T020102	868181208GA1N8



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812083270	08681812083270	NEUROSURGERY DRAPE KIT -10 (BEYİN CERRAHİ ÖRTÜ SETİ-10)	RMD-332-10	T0202	868181208TD01HS
8681812083287	08681812083287	ABORTION DRAPE KIT -2 (KÜRTAJ ÖRTÜ SETİ-2)	BİO-KÖ100-2	T0202	868181208TD01HS
8681812083294	08681812083294	ABORTION DRAPE KIT -3 (KÜRTAJ ÖRTÜ SETİ-3)	BİO-KÖ100-3	T0202	868181208TD01HS
8681812083300	08681812083300	L DRAPE -2 (L ÖRTÜSÜ-2)	BİO-LÖ100-2	T020102	868181208GA1N8
8681812083317	08681812083317	L DRAPE -3 (L ÖRTÜSÜ-3)	BİO-LÖ100-3	T020102	868181208GA1N8
8681812083324	08681812083324	LAMINECTOMY DRAPE KIT -2 (LAMİNEKTOMİ ÖRTÜ SETİ-2)	BİO-LMÖ100-2	T0202	868181208TD01HS
8681812083331	08681812083331	LAMINECTOMY DRAPE KIT -3 (LAMİNEKTOMİ ÖRTÜ SETİ-3)	BİO-LMÖ100-3	T0202	868181208TD01HS
8681812083348	08681812083348	LAPAROTOMY DRAPE KIT -2 (LAPAROTOMİ ÖRTÜ SETİ-2)	RMD-328-2	T0202	868181208TD01HS
8681812083355	08681812083355	LAPAROTOMY DRAPE KIT -3 (LAPAROTOMİ ÖRTÜ SETİ-3)	RMD-328-3	T0202	868181208TD01HS
8681812083362	08681812083362	LAPAROTOMY DRAPE KIT -4 (LAPAROTOMİ ÖRTÜ SETİ-4)	RMD-328-4	T0202	868181208TD01HS
8681812083379	08681812083379	LAPAROTOMY DRAPE KIT -5 (LAPAROTOMİ ÖRTÜ SETİ-5)	RMD-328-5	T0202	868181208TD01HS
8681812083386	08681812083386	LAPAROTOMY DRAPE -2 (LAPAROTOMİ ÖRTÜSÜ -2)	RMD-328-6	T020102	868181208GA1N8
8681812083393	08681812083393	LAPAROTOMY DRAPE -3 (LAPAROTOMİ ÖRTÜSÜ -3)	RMD-328-7	T020102	868181208GA1N8
8681812083409	08681812083409	LAPAROSCOPY DRAPE KIT -2 (LAPOROSKOPİ ÖRTÜ SETİ-2)	RMD-329-2	T0202	868181208TD01HS
8681812083416	08681812083416	LAPAROSCOPY DRAPE KIT -3 (LAPOROSKOPİ ÖRTÜ SETİ-3)	RMD-329-3	T0202	868181208TD01HS
8681812083423	08681812083423	LAPAROSCOPY DRAPE KIT -4 (LAPOROSKOPİ ÖRTÜ SETİ-4)	RMD-329-4	T0202	868181208TD01HS



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812083430	08681812083430	LAPAROSCOPY DRAPE KIT -5 (LAPOROSKOPI ÖRTÜ SETİ-5)	RMD-329-5	T0202	868181208TD01HS
8681812083447	08681812083447	LAPAROSCOPY DRAPE -2 (LAPOROSKOPI ÖRTÜSÜ -2)	RMD-329-11	T020102	868181208GA1N8
8681812083454	08681812083454	LAPAROSCOPY DRAPE -3 (LAPOROSKOPI ÖRTÜSÜ -3)	RMD-329-12	T020102	868181208GA1N8
8681812083461	08681812083461	LASER EYE DRAPE KIT -2 (LAZER GÖZ ÖRTÜ SETİ-2)	RMD-337-2	T0202	868181208TD01HS
8681812083478	08681812083478	LASER EYE DRAPE KIT -3 (LAZER GÖZ ÖRTÜ SETİ-3)	RMD-337-3	T0202	868181208TD01HS
8681812083485	08681812083485	LITHOTOMY DRAPE KIT -2 (LİTOTOMY ÖRTÜ SETİ-2)	BİO-LÖS100-2	T0202	868181208TD01HS
8681812083492	08681812083492	LITHOTOMY DRAPE KIT -3 (LİTOTOMY ÖRTÜ SETİ-3)	BİO-LÖS100-3	T0202	868181208TD01HS
8681812083614	08681812083614	O.P.U. DRAPE KIT -2 (O.P.U. ÖRTÜ SETİ-2)	RMD-325-2	T0202	868181208TD01HS
8681812083621	08681812083621	O.P.U. DRAPE KIT -3 (O.P.U. ÖRTÜ SETİ-3)	RMD-325-3	T0202	868181208TD01HS
8681812083638	08681812083638	O.P.U. DRAPE KIT -4 (O.P.U. ÖRTÜ SETİ-4)	RMD-325-4	T0202	868181208TD01HS
8681812083645	08681812083645	O.P.U. DRAPE KIT -5 (O.P.U. ÖRTÜ SETİ-5)	RMD-325-5	T0202	868181208TD01HS
8681812083652	08681812083652	O.P.U. DRAPE KIT -6 (O.P.U. ÖRTÜ SETİ-6)	RMD-325-6	T0202	868181208TD01HS
8681812083669	08681812083669	O.P.U. DRAPE KIT -7 (O.P.U. ÖRTÜ SETİ-7)	RMD-325-7	T0202	868181208TD01HS
8681812083676	08681812083676	O.P.U. DRAPE KIT -8 (O.P.U. ÖRTÜ SETİ-8)	RMD-325-8	T0202	868181208TD01HS
8681812083683	08681812083683	O.P.U. DRAPE KIT -9 (O.P.U. ÖRTÜ SETİ-9)	RMD-325-9	T0202	868181208TD01HS



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812083843	08681812083843	PERCUTANEOUS DRAPE -3 (PERKÜTAN ÖRTÜSÜ -3)	RMD-334-12	T020102	868181208GA1N8
8681812083850	08681812083850	REFRACTOR DRAPE -2 (REFRAKTÖR ÖRTÜSÜ -2)	RMD-RF-2	T020102	868181208GA1N8
8681812083867	08681812083867	REFRACTOR DRAPE -3 (REFRAKTÖR ÖRTÜSÜ -3)	RMD-RF-3	T020102	868181208GA1N8
8681812083874	08681812083874	REFRACTOR DRAPE -4 (REFRAKTÖR ÖRTÜSÜ -4)	RMD-RF-4	T020102	868181208GA1N8
8681812083881	08681812083881	REFRACTOR DRAPE -5 (REFRAKTÖR ÖRTÜSÜ -5)	RMD-RF-5	T020102	868181208GA1N8
8681812083898	08681812083898	CESAREAN DRAPE KIT -2 (SEZERYAN ÖRTÜ SETİ-2)	RMD-324-2	T0202	868181208TD01HS
8681812083904	08681812083904	CESAREAN DRAPE KIT -3 (SEZERYAN ÖRTÜ SETİ-3)	RMD-324-3	T0202	868181208TD01HS
8681812083911	08681812083911	CESAREAN DRAPE KIT -4 (SEZERYAN ÖRTÜ SETİ-4)	RMD-324-4	T0202	868181208TD01HS
8681812083928	08681812083928	CESAREAN DRAPE KIT -5 (SEZERYAN ÖRTÜ SETİ-5)	RMD-324-5	T0202	868181208TD01HS
8681812083935	08681812083935	CESAREAN DRAPE KIT -6 (SEZERYAN ÖRTÜ SETİ-6)	RMD-324-6	T0202	868181208TD01HS
8681812083942	08681812083942	CESAREAN DRAPE KIT -7 (SEZERYAN ÖRTÜ SETİ-7)	RMD-324-7	T0202	868181208TD01HS
8681812083959	08681812083959	CESAREAN DRAPE KIT -8 (SEZERYAN ÖRTÜ SETİ-8)	RMD-324-8	T0202	868181208TD01HS
8681812083966	08681812083966	CESAREAN DRAPE KIT -9 (SEZERYAN ÖRTÜ SETİ-9)	RMD-324-9	T0202	868181208TD01HS
8681812083973	08681812083973	CESAREAN DRAPE KIT -10 (SEZERYAN ÖRTÜ SETİ-10)	RMD-324-10	T0202	868181208TD01HS
8681812083980	08681812083980	CESAREAN DRAPE KIT -11 (SEZERYAN ÖRTÜ SETİ-11)	RMD-324-11	T0202	868181208TD01HS



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812083997	08681812083997	CESAREAN DRAPE KIT -12 (SEZERYAN ÖRTÜ SETİ-12)	RMD-324-12	T0202	868181208TD01HS
8681812084000	08681812084000	CESAREAN DRAPE KIT -13 (SEZERYAN ÖRTÜ SETİ-13)	RMD-324-13	T0202	868181208TD01HS
8681812084017	08681812084017	CESAREAN DRAPE KIT -14 (SEZERYAN ÖRTÜ SETİ-14)	RMD-324-14	T0202	868181208TD01HS
8681812084024	08681812084024	CESAREAN DRAPE KIT -15 (SEZERYAN ÖRTÜ SETİ-15)	RMD-324-15	T0202	868181208TD01HS
8681812084031	08681812084031	CESAREAN DRAPE -2 (SEZERYAN ÖRTÜSÜ -2)	RMD-324-16	T020102	868181208GA1N8
8681812084048	08681812084048	CESAREAN DRAPE -3 (SEZERYAN ÖRTÜSÜ -3)	RMD-324-17	T020102	868181208GA1N8
8681812084055	08681812084055	CYSTOSCOPY DRAPE KIT -2 (SİSTOSKOPI ÖRTÜ SETİ-2)	RMD-336-2	T0202	868181208TD01HS
8681812084062	08681812084062	CYSTOSCOPY DRAPE KIT -3 (SİSTOSKOPI ÖRTÜ SETİ-3)	RMD-336-3	T0202	868181208TD01HS
8681812084079	08681812084079	SCOPY CASE -2 (SKOPI KILIFI-2)	BİO-SKOPI-2	T030102	868181208PS1RB
8681812084086	08681812084086	SCOPY CASE -3 (SKOPI KILIFI-3)	BİO-SKOPI-3	T030102	868181208PS1RB
8681812084093	08681812084093	SCOPY CASE -4 (SKOPI KILIFI-4)	BİO-SKOPI-4	T030102	868181208PS1RB
8681812084109	08681812084109	SCOPY CASE -5 (SKOPI KILIFI-5)	BİO-SKOPI-5	T030102	868181208PS1RB
8681812084116	08681812084116	SCOPY CASE C SLEEVE -1 (SKOPI KILIFI C KOLLU-1)	BİO-SC100-1	T030102	868181208PS1RB
8681812084123	08681812084123	SCOPY CASE C SLEEVE -2 (SKOPI KILIFI C KOLLU-2)	BİO-SC100-2	T030102	868181208PS1RB
8681812084130	08681812084130	SCOPY CASE C SLEEVE -3 (SKOPI KILIFI C KOLLU-3)	BİO-SC100-3	T030102	868181208PS1RB
8681812084147	08681812084147	SCOPY CASE C SLEEVE -4 (SKOPI KILIFI C KOLLU-4)	BİO-SC100-4	T030102	868181208PS1RB
8681812084154	08681812084154	SCOPY CASE C SLEEVE -5 (SKOPI KILIFI C KOLLU-5)	BİO-SC100-5	T030102	868181208PS1RB



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812084161	08681812084161	SPINAL DRAPE KIT -2 (SPİNAL ÖRTÜ SETİ-2)	BiO-SP100-2	T0202	868181208TD01HS
8681812084178	08681812084178	SPINAL DRAPE KIT -3 (SPİNAL ÖRTÜ SETİ-3)	BiO-SP100-3	T0202	868181208TD01HS
8681812084185	08681812084185	SPINAL DRAPE KIT -4 (SPİNAL ÖRTÜ SETİ-4)	BiO-SP100-4	T0202	868181208TD01HS
8681812084192	08681812084192	SPINAL DRAPE KIT -5 (SPİNAL ÖRTÜ SETİ-5)	BiO-SP100-5	T0202	868181208TD01HS
8681812084208	08681812084208	STANDARD SURGERY GOWN XXL (STANDART CERRAHİ ÖNLÜK XXL)	SRCÖ-35MUMS-125	T020401	868181208SS1RS
8681812084215	08681812084215	STANDARD SURGERY GOWN XXXL (STANDART CERRAHİ ÖNLÜK XXXL)	SRCÖ-35MUMS-125	T020401	868181208SS1RS
8681812084222	08681812084222	STERIL ANGIOGRAPHY KIT FEMORAL - H.P.-2 (STERİL ANJİO SETİ FEMORAL- H.P.-2)	RMD-363-2	T0202	868181208TD01HS
8681812084239	08681812084239	STERIL ANGIOGRAPHY KIT FEMORAL - H.P. -3 (STERİL ANJİO SETİ FEMORAL- H.P.-3)	RMD-363-3	T0202	868181208TD01HS
8681812084246	08681812084246	STERIL ANGIOGRAPHY KIT FEMORAL - H.P. -4 (STERİL ANJİO SETİ FEMORAL- H.P.-4)	RMD-363-4	T0202	868181208TD01HS
8681812084253	08681812084253	STERIL ANGIOGRAPHY KIT FEMORAL - H.P. -5 (STERİL ANJİO SETİ FEMORAL- H.P.-5)	RMD-363-5	T0202	868181208TD01HS
8681812084260	08681812084260	STERIL ANGIOGRAPHY KIT PANELED FEMORAL - H.P. (STERİL ANJİO SETİ PANELLİ FEMORAL- H.P.)	RMD-372-2	T0202	868181208TD01HS
8681812084277	08681812084277	STERIL ANGIOGRAPHY KIT PANELED FEMORAL - H.P. (STERİL ANJİO SETİ PANELLİ FEMORAL- H.P.)	RMD-372-3	T0202	868181208TD01HS
8681812084284	08681812084284	STERIL ANGIOGRAPHY KIT	RMD-372-4	T0202	868181208TD01HS

Declaration Of Conformity

		SETİ-2)			
8681812084420	08681812084420	T.U.R. DRAPE KIT -3 (T.U.R. ÖRTÜ SETİ-3)	RMD-335-3	T0202	868181208TD01HS
8681812084437	08681812084437	T.U.R. DRAPE KIT -4 (T.U.R. ÖRTÜ SETİ-4)	RMD-335-4	T0202	868181208TD01HS
8681812084444	08681812084444	T.U.R. DRAPE KIT -5 (T.U.R. ÖRTÜ SETİ-5)	RMD-335-5	T0202	868181208TD01HS
8681812084451	08681812084451	T.U.R. DRAPE KIT -6 (T.U.R. ÖRTÜ SETİ-6)	RMD-335-6	T0202	868181208TD01HS
8681812084468	08681812084468	T.U.R. DRAPE KIT -7 (T.U.R. ÖRTÜ SETİ-7)	RMD-335-7	T0202	868181208TD01HS
8681812084475	08681812084475	T.U.R. DRAPE KIT -8 (T.U.R. ÖRTÜ SETİ-8)	RMD-335-8	T0202	868181208TD01HS
8681812084482	08681812084482	T.U.R. DRAPE KIT -9 (T.U.R. ÖRTÜ SETİ-9)	RMD-335-9	T0202	868181208TD01HS
8681812084499	08681812084499	T.U.R. DRAPE KIT -10 (T.U.R. ÖRTÜ SETİ-10)	RMD-335-10	T0202	868181208TD01HS
8681812084505	08681812084505	T.U.R. DRAPE KIT -11 (T.U.R. ÖRTÜ SETİ-11)	RMD-335-11	T0202	868181208TD01HS
8681812084512	08681812084512	T.U.R. DRAPE KIT -12 (T.U.R. ÖRTÜ SETİ-12)	RMD-335-12	T0202	868181208TD01HS
8681812084529	08681812084529	T.U.R. DRAPE KIT -13 (T.U.R. ÖRTÜ SETİ-13)	RMD-335-13	T0202	868181208TD01HS
8681812084536	08681812084536	T.U.R. DRAPE KIT-14 (T.U.R. ÖRTÜ SETİ-14)	RMD-335-14	T0202	868181208TD01HS
8681812084543	08681812084543	T.U.R. DRAPE KIT-15 (T.U.R. ÖRTÜ SETİ-15)	RMD-335-15	T0202	868181208TD01HS
8681812084550	08681812084550	T.U.R. DRAPE -2 (T.U.R. ÖRTÜSÜ-2)	RMD-335-16	T020102	868181208GA1N8
8681812084567	08681812084567	T.U.R. DRAPE -3 (T.U.R. ÖRTÜSÜ-3)	RMD-335-17	T020102	868181208GA1N8
8681812084574	08681812084574	T.U.R. DRAPE -4 (T.U.R. ÖRTÜSÜ-4)	RMD-335-18	T020102	868181208GA1N8

Declaration Of Conformity



Declaration Of Conformity

Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812085007	08681812085007	VERTICAL INSULATION DRAPE -5 (VERTİKAL İZOLASYON ÖRTÜSÜ-5)	BiO-ViO100-5	T020102	868181208GA1N8
8681812085014	08681812085014	VARSITY DRAPE KIT -1 (VARİS ÖRTÜ SETİ-1)	BiO-VOS-1	T0202	868181208TD01HS
8681812085021	08681812085021	VARSITY DRAPE KIT -2 (VARİS ÖRTÜ SETİ-2)	BiO-VOS-2	T0202	868181208TD01HS
8681812085038	08681812085038	VARSITY DRAPE KIT -3 (VARİS ÖRTÜ SETİ-3)	BiO-VOS-3	T0202	868181208TD01HS
8681812083355	08681812083355	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-120	T0202	868181208TD01HS
8681812083362	08681812083362	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-121	T0202	868181208TD01HS
8681812083379	08681812083379	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-122	T0202	868181208TD01HS
8681812083386	08681812083386	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-123	T0202	868181208TD01HS
8681812083393	08681812083393	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-124	T0202	868181208TD01HS
8681812083409	08681812083409	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-125	T0202	868181208TD01HS
8681812083416	08681812083416	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-170	T0202	868181208TD01HS
8681812083423	08681812083423	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-172	T0202	868181208TD01HS
8681812083430	08681812083430	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-173	T0202	868181208TD01HS
8681812083447	08681812083447	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-174	T0202	868181208TD01HS
8681812083454	08681812083454	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-175	T0202	868181208TD01HS



Document No	TF.01.02
Revision No	02
Revision Date	16.07.2024
Issue Date	18.10.2022
Page	

8681812083461	08681812083461	ANGIOGRAPHY DRAPE KIT (ANJİOGRAFİ ÖRTÜ SETİ)	RMD-310-1S	T0202	868181208TD01HS
8681812083478	08681812083478	BY-PASS DRAPE KIT (BY-PASS ÖRTÜ SETİ)	RMD-311-16S	T0202	868181208TD01HS
8681812083485	08681812083485	CARDIOVASCULAR DRAPE KIT (KARDİOVASKÜLER ÖRTÜ SETİ)	RMD-313-100	T0202	868181208TD01HS
8681812083492	08681812083492	CARDIOVASCULAR DRAPE KIT (KARDİOVASKÜLER ÖRTÜ SETİ)	RMD-313-101	T0202	868181208TD01HS
8681812083508	08681812083508	CARDIOVASCULAR DRAPE KIT (KARDİOVASKÜLER ÖRTÜ SETİ)	RMD-313-102	T0202	868181208TD01HS
8681812083515	08681812083515	ARTHROPLASTY DRAPE KIT (ARTROSKOPİ ÖRTÜ SETİ)	RMD-314-104	T0202	868181208TD01HS
8681812083522	08681812083522	ARTHROPLASTY DRAPE KIT (ARTROSKOPİ ÖRTÜ SETİ)	RMD-314-105	T0202	868181208TD01HS
8681812083539	08681812083539	KNEE DRAPE KIT (DİZ ÖRTÜ SETİ)	RMD-316-100	T0202	868181208TD01HS
8681812083546	08681812083546	ARTHROPLASTY (HIP) DRAPE KIT (ARTROPLASTİ (KALÇA) ÖRTÜ SETİ)	RMD-318-101	T0202	868181208TD01HS
8681812083553	08681812083553	MATERNITY DRAPE KIT (DOĞUM ÖRTÜ SETİ)	RMD-323-116	T0202	868181208TD01HS
8681812083560	08681812083560	GENERAL SURGERY DRAPE KIT (GENEL CERRAHİ ÖRTÜ SETİ)	RMD-326-114	T0202	868181208TD01HS
8681812083577	08681812083577	GENERAL SURGERY DRAPE KIT (GENEL CERRAHİ ÖRTÜ SETİ)	RMD-326-115	T0202	868181208TD01HS
8681812083584	08681812083584	GENERAL SURGERY DRAPE KIT (GENEL CERRAHİ ÖRTÜ SETİ)	RMD-326-116	T0202	868181208TD01HS
8681812083591	08681812083591	GENERAL SURGERY DRAPE KIT (GENEL CERRAHİ ÖRTÜ SETİ)	RMD-326-125	T0202	868181208TD01HS
8681812083607	08681812083607	GENERAL SURGERY DRAPE KIT (GENEL CERRAHİ ÖRTÜ SETİ)	RMD-326-128	T0202	868181208TD01HS
8681812083614	08681812083614	GENERAL SURGERY DRAPE KIT	RMD-326-129	T0202	868181208TD01HS

**BIOTEX MEDİKAL TEKSTİL İTH.
İHR. SAN. VE TİC. A.Ş.**
Merkez : İstanbul Mah. 2 Nolu Sehiler Cad.
İçişleri İşleri Mah. 2 Nolu 41/G Merkez / Rize
Tic. Sic. No: 215555 Fax: 0464 213 16 38
Etiler Mah. 3 Nolu Cad. No: 14
Kalkınma A.Ş. Tel: 0464 300 01 01
Kalkınma A.Ş. 521 Tic. Sic. No: 8456
Yedigöller V.D. 700041552100001
Mersis No: 700041552100001

Declaration Of Conformity

	Declaration Of Conformity	Document No	TF.01.02
		Revision No	02
		Revision Date	16.07.2024
		Issue Date	18.10.2022
		Page	

		PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELLİ))			
8681812083782	08681812083782	ANGIOGRAPHY DRAPE KIT (WITH PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELLİ))	RMD-310-2P	T0202	868181208TD01HS
8681812083799	08681812083799	ANGIOGRAPHY DRAPE KIT (WITH PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELLİ))	RMD-310-3P	T0202	868181208TD01HS
8681812083805	08681812083805	ANGIOGRAPHY DRAPE KIT (WITH PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELLİ))	RMD-310-4P	T0202	868181208TD01HS
8681812083812	08681812083812	ANGIOGRAPHY DRAPE KIT (WITH PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELLİ))	RMD-310-5P	T0202	868181208TD01HS
8681812083829	08681812083829	ANGIOGRAPHY DRAPE KIT (WITHOUT PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELSİZ))	RMD-310-1PS	T0202	868181208TD01HS
8681812083836	08681812083836	ANGIOGRAPHY DRAPE KIT (WITHOUT PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELSİZ))	RMD-310-2PS	T0202	868181208TD01HS
8681812083843	08681812083843	ANGIOGRAPHY DRAPE KIT (WITHOUT PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELSİZ))	RMD-310-3PS	T0202	868181208TD01HS
8681812083850	08681812083850	ANGIOGRAPHY DRAPE KIT (WITHOUT PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELSİZ))	RMD-310-4PS	T0202	868181208TD01HS
8681812083867	08681812083867	ANGIOGRAPHY DRAPE KIT (WITHOUT PANEL) (ANJİOGARFİ ÖRTÜ SETİ (PANELSİZ))	RMD-310-5PS	T0202	868181208TD01HS

Applied Standards:

BIOTEX MEDİKAL TEKSTİL İTH.
 İHR. SAN. VE TİC. A.Ş.
 Merkez : İstanbul / Beşiktaş / Nispetiye / 2 Nolu Şehitler Cad.
 İşletme : İstanbul / Beşiktaş / 41/G Merkez / Rıza
 Telli Sok. No: 21 / Kat: 3 / Tel: 0464 213 16 38
 Etiler / Beşiktaş / İstanbul / Türkiye / Fax: 0464 213 16 38
 Etiler / Beşiktaş / İstanbul / Türkiye / Tel: 0464 200 01 01
 Yayıncılık V.D.: 0464 213 16 38 / Tic. Sic. No: 9456
 Mersis No: 340401552100001

	Declaration Of Conformity	Document No	TF.01.02
		Revision No	02
		Revision Date	16.07.2024
		Issue Date	18.10.2022
		Page	

EN ISO 14971: 2019, EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 11135:2014, EN ISO 13795-1:2019, Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC, Medical Device Directive Annex II, 2017/745 MDR Medical Device Regulation

Rev. No	Rev. Date	Revision History
00		The first publish according to MDR.
02	16.07.2024	EMDN and BASIC-UDI-DI codes are defined
Authorized Personnel		Place / Date
Ahmet Turan ÖKSÜZ		Rize / 16.07.2024

BIOTEX MEDİKAL TEKSTİL İTH.
 İHR. SAN. VE TİC. A.Ş.
 Merkez : İstanbul - Mah. 2 Nolu Şehitler Cad.
 İsmail Paşa İş Merkezi Kat: 41/G Merkez / Rize
 Tel: 0464 213 30 38 Fax: 0464 213 16 38
 Şişli: Akmerkezi Kat: 3 nolu Cad no:14
 Kallandere Kat: 521 Tic. Sic.No: 8456
 Yeşilçay V.D.: Kat: 521 Tic. Sic.No: 8456
 Mersis No: 70041552100001