BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

UYGUNLUK DEKLARASYONU
DECLARATION OF CONFORMITY
(Sınıf/ Class **IIb, IIa, Is, Im)**

Doküman Numarası Document Number	DoC-TK2	**Revizyon No:** 34 Revision No	**Tarih:** 07.10.2022 Date
Üretici Firma Manufacturer	BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş.		
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BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş. Yetkili otorite TÜV NORD CERT GmbH (N° 0044) tarafından değerlendirmiştir.
Bu deklerasyon, Tıbbi Cihaz Direktifi 93/42 EEC Ek VII ve Düzeltme 2007/47/EEC ile uyumlu olarak hazırlanmıştır.

BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş. having been assessed by TÜV NORD CERT GmbH Notified Body N° 0044.
This declaration is made in accordance with Annex VII of the Medical Devices Directive 93/42 EEC and Amendment 2007/47/EEC

Uygunluk deklarasyonunda bulunan bütün ürünler için/For all products which are mentioned in the DoC.

Sertifikalar Certificates	**Sertifika No** Certicate No	**Veriliş Tarihi** Date of Issue	**Son Kullanma Tarihi** Expiry Date
EN ISO 13485 (*)	04 221 980886	27.07.2022	26.05.2024
93/42 EEC Ek II / Annex II (4 hariç /without 4)	04 232 980886	16.04.2020	16.09.2023

(*) EN ISO 13485: 2016 Tıbbi Cihazlar- Kalite Yönetim Sistemleri- Ruhsatlandırma Amaçlı Gereklilikler / Medical Devices-Quality Management Systems- Requirements for Regulatory Purposes

Bıçakcılar Tıbbi Cihazlar A.Ş, Tıbbi Cihazlar Direktifinin 93/42 EEC ve Ek 2007/47/EEC Ek II maddelerine uygun olarak aşağıda belirtilen ürünler için bütün sorumluluğu üstlenir ve ürünün aşağıda belirtilen standardlara ya da diğer düzenleyici mevzuatlara uygunluğunu deklare eder.
Bıçakcılar Tıbbi Cihazlar A.Ş, Declare under our sole responsibility that the products below to which this declaration relates are in conformity with the following standards or other regulatory laws following the provisions of Medical Device Directive 93/42 EEC and Amendment 2007/47/EEC Annex II.

- **ISO 9001: 2015 Kalite Yönetim Sistemleri – Gereklilikler/** Quality Management Systems- Requirements
- **EN ISO 13485: 2016 Tıbbi Cihazlar- Kalite Yönetim Sistemleri – Mevzuat Amaçları Bakımından Şartlar /** Medical Devices- Quality Management Systems-Requirements for Regulatory Purposes
- **EN ISO 14971 Tıbbi cihazlar – Tıbbi cihazlara risk yönetiminin uygulanması** / Medical devices - Application of risk management to medical devices
- **ISO/TR 24971 Tıbbi cihazlar - ISO 14971'in uygulanmasına ilişkin kılavuz /** Medical devices — Guidance on the application of ISO 14971
- **EN ISO 10993 Tıbbi cihazların Biyolojik Değerlendirilmesi /** Biological Evaluation of Medical Devices
- **EN ISO 11135 Sağlık Malzemelerinin Sterilizasyonu-Etilenoksit /** Sterilization of Heathcare products-Ethylene oxide
- **EN ISO 11607 Son Olarak Steril Edilen Tıbbi Cihazlar için Ambalajlama/** Packaging for terminally sterilized medical device

- **EN ISO 11737 Tıbbi Cihazların Sterilizasyonu-Mikrobiyolojik Metodlar** /Sterilization of medical devices -- Microbiological methods

- **ISO 20417 Tıbbi cihazlar - İmalatçı tarafından sağlanacak bilgiler /** Medical devices — Information to be supplied by the manufacturer
- **EN ISO 15223 Tıbbi cihazlar - Tıbbi cihaz etiketlerinde, etiketlemede ve sunulacak bilgide kullanılacak semboller /** Medical devices — Symbols to be used with information to be supplied by the manufacturer
- **EN ISO 11138 Sağlık Bakım Ürünlerinin Sterilizasyonu- Biyolojik İndikatörler /** Sterilization Of Health Care Products - Biological Indicators / Sterilization Of Health Care Products - Biological Indicators
- **EN ISO 14644 Temiz odalar ve bunlarla ilgili kontrollü ortamlar** / Cleanrooms and associated controlled environments
- **ISO/TR 20416 Tıbbî cihazlar - Üreticiler için Pazar Arz Sonrası Gözetim/** Medical devices — Post-market surveillance for manufacturers
- **EN 62366-1 Tıbbi cihazlar - Bölüm 1: Kullanılabilirlik tekniğinin tıbbi cihazlara uygulanması** / Medical devices - Part 1: Application of usability engineering to medical devices
- **IEC 62366-2 Tıbbi cihazlar - Bölüm 2: Kullanılabilirlik tekniğinin tıbbi cihazlara uygulanmasına ilişkin rehberlik /** Medical devices — Part 2: Guidance on the application of usability engineering to medical devices
- **MDCG 2020-6 Eski cihazlar için yeterli klinik kanıt hakkında rehberlik /** Guidance on sufficient clinical evidence for legacy devices
- **MDCG 2021-25 MDR gerekliliklerinin "eski cihazlara" ve 90/385/EEC veya 93/42/EEC Direktifleri uyarınca 26 Mayıs 2021'den önce piyasaya sürülen cihazlara uygulanması /** Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

Sınıf IIb Ürünler / *Class IIb Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	157 00XX 1 015 20XX 1 157 00XX 1G 015 20XX 1G	Lökosit Filtre Seti *Leukocyte Filter Set*	35071	Steril *Sterile*	ANSI/AAMI BF 64:2012	Kural 3 / Rule 3 Kural18 / Rule 18
2	040 XXXX 1 400 XXXX 1	Basınç İzleme Seti *Pressure Monitoring Set*	35529	Steril *Sterile*	ISO 8536-4: 2019 EN 60601-1:2006/A1:2013 EN 60601-2-34: 2014	Kural 10 Rule 10

Sınıf IIa Ürünler / *Class IIa Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	015 0102 1	Arteriyal İğne *Arterial Needle*	12747	Steril *Sterile*	EN ISO 80369-7 (2016)	Kural 6 Rule 6
2	104 1001 1 010 2XXX 1	Infüzyon pompa seti *Infusion pump set*	35833	Steril *Sterile*	ISO 8536-4 (2019) EN ISO 8536-8 (2015)	Kural 2 Rule 2

3	113 XXXX 1 114 XXXX 1	IV Filtre Seti *IV Filter Set*	35072	Steril *Sterile*	ISO 8536-4 (2019) ISO 80369-7 (2016)	Kural 3 Rule 3
4	115 0101 1	Eksternal Drenaj Büret- 150ml *External Drainage Burette-150ml*	61796	Steril *Sterile*	ISO 8536-5 (2004) ISO 20697 (2018)	Kural 2 Rule 2
5	115 0111 1	Eksternal Drenaj Büret-150ml Plakalı *External Drainage Burette-150ml - W/plate*	61796	Steril *Sterile*	ISO 8536-5 (2004) ISO 20697 (2018)	Kural 2 Rule 2
6	123 1XXX 1	Üç yollu musluklu uzatma *Extention Line w/ Three way Stopcock*	12170	Steril *Sterile*	ISO 80369-7 (2016) ISO 8536-9 (2015)	Kural 2 Rule 2
7	145 XXXX 1 146 XXXX 1 014 XXXX 1 095 10XX 1	B-CAT I.V Kanül *B-CAT I.V Cannula*	34905	Steril *Sterile*	EN ISO 10555-1 (2013-A1:2018) EN ISO 10555-5 (2013) ISO 80369-7 (2016)	Kural 7 Rule 7
8	150 XXXX 1 151 XXXX 1 154 XXXX 1 155 XXXX 1 015 00XX 1 095 12XX 1	Kan Transfüzyon Seti *Blood Transfusion Set*	38569	Steril *Sterile*	ISO 80369-7 (2016) ISO 1135-4 (2015)	Kural 2 Rule 2
9	155 XXXX 1 156 XXXX 1	Mikroagregat Filtre Seti *Microaggregate Filter Set*	35071	Steril *Sterile*	ISO 1135-4 (2015)	Kural 3 Rule 3
10	160 XXXX 1 161 XXXX 1 016 XXXX 1	Yankauer Aspirasyon Ucu *Yankauer Suction Handle*	35917	Steril *Sterile*	NA	Kural 6 Rule 6
11	162 XXXX 1	Aspiratör ucu *Suction wand*	35917	Steril *Sterile*	NA	Kural 6 Rule 6
12	164 XXXX 1 165 XXXX 1 166 XXXX 1 167 XXXX 1 168 XXXX 1	Yankauer Aspirasyon Seti *Yankauer Suction Set*	35917	Steril *Sterile*	ISO 20697 (2018) ISO 8836 (2019)	Kural 6 Rule 6
13	168 XXXX X 169 XXXX 1	Aspirasyon Bağlantı Hortumu *Suction Connecting Tube*	16779	Steril *Sterile*	ISO 20697 (2018)	Kural 6 Rule 6
14	173 XXXX 1 017 XXXX 1 171 XXXX 1	B-Vak Doku Drenaj Seti B-Vak Mini Doku Drenaj Seti *B-Vak Wound Drainage Set* *B-Vak Mini Wound Drainage Set*	35824	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
15	017 11XX 1	Redon Dren-Trokar *Redon Drain-Trochar*	11305	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7

16	180 XXXX 1 182 XXXX 1	Toraks Kateteri – Genişleyen Uçlu *Thoracic Catheter w/Flared End*	47796	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
17	181 XX01 1 183 XX01 1	Toraks Kateteri – Tut Çek Konnektörlü Uç *Thoracic Catheter w/Pull Through End*	47796	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
18	184 XXXX 1	Toraks Kateteri Trokarlı *Thoracic Catheter w/Throcar*	47796	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
19	189 XXXX 1 019 XXXX 1	Aspirasyon Kateteri (Kapkon Konnektörlü) *Suction Catheter (w/Kapkon connector)*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
20	190 XXXX 1 191 XX17 1 019 XXXX 1	Aspirasyon Kateteri *Suction Catheter*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
21	191 XX11 1 019 XXXX 1	Aspirasyon Kateteri-Vakum Kontrollü *Suction Catheter w/Vacuum Control Connector*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
22	019 535X 1	Aspirasyon Kateteri Vakum Kontrollü Konnektör Kesik Uç Delikli *Suction Catheter, w/Vacuum Control Connector Beveled Tip w/Hole*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
23	190 XXXX 1 191 XXXX 1 019 XXXX 1	Aspirasyon Kateteri- Kılıflı Aspirasyon Kateteri- Kılıflı, Eğimli Uç Aspirasyon Kateteri-Vakum Kontrollü *Sleeved Suction Catheter* *Sleeved Suction Catheter,* *Beveled Tip* *Suction Catheter w/Vacuum Control Connector*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
24	193 XXXX 1 019 XXXX 1	Mide Kateteri *Stomach Catheter*	35415	Steril *Sterile*	NA	Kural 5 Rule 5
25	194 XXXX 1 019 XXXX 1	Nazogastrik Kateter *Nasogastric Catheter*	14221	Steril *Sterile*	NA	Kural 5 Rule 5
26	195 XX01 1 195 XX05 1 019 XXXX 1	Nelaton Kateter Nelaton Female Kateter *Nelaton Catheter* *Nelaton Female Catheter*	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5
27	195 XX20 1 019 XXXX 1	Tiemann Kateteri *Tiemann Catheter*	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5

28	196 XXXX 1	B-Soft Hidrofilik Kaplı Kateter *B-Soft Hydrophilic Coated Catheter*	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5
29	196 XX21 1	B-SOFT Kit	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5
30	197 XXXX 1 019 XXXX 1	Beslenme Kateteri *Feeding Catheter*	14221	Steril *Sterile*	NA	Kural 5 Rule 5
31	197 XX21 1	Beslenme Kateteri- Enfit Konnektörlü *Feeding Catheter- w/ Enfit Connector*	14221	Steril *Sterile*	ISO 20695 (2020)	Kural 5 Rule 5
32	198 XXXX 1 019 XXXX 1	Göbek Kateteri *Umbilical Catheter*	10759	Steril *Sterile*	ISO 80369-7 (2016) EN ISO 10555-1 (2013-A1:2018)	Kural 7 Rule 7
33	199 XXXX 1 019 XXXX 1	Rektal Kateter *Rectal Catheter*	46202	Steril *Sterile*	EN 12439 (1999)	Kural 5 Rule 5
34	300 XXXX 1 304 XXXX 1 310 XXXX 1 311 XXXX 1 312 XXXX 1 315 XXXX 1 776 4001 1 030 XXXX 1 032 XXXX 1	Ekstrakorporeal Tüp Set *Extracorporeal Tubing Set*	35441	Steril *Sterile*	ISO 15676 (2016) ISO 80369-7 (2016)	Kural 2 Rule 2
35	305 XXXX X 306 XXXX X 307 XXXX X 030 XXXX 1	Ekstrakorporeal PVC Hortum *Extracorporeal PVC Tubing*	46721	Steril *Sterile*	ISO 15676 (2016)	Kural 2 Rule 2
36	320 XXXX 1 032 XXXX 1	Hızlı Doldurma Seti *Quick Prime Set*	35441	Steril *Sterile*	ISO 15676 (2016)	Kural 2 Rule 2
37	323 XXXX 1	Y Adaptör / Perfüzyon Y-Adaptör *Y Adapter / Perfusion Y-Adapter*	58824	Steril *Sterile*	NA	Kural 2 Rule 2
38	325 XXXX 1 032 XXXX 1	Kardiopleji Set *Cardioplegia Set*	16163	Steril *Sterile*	ISO 80369-7 (2016) ISO 1135-4 (2015)	Kural 2 Rule 2
39	330 0XXX 1	Vent Kateter *Vent Catheter*	17613	Steril *Sterile*	ISO 20697 (2018) ISO 80369-7 (2016)	Kural 7 Rule 7
40	330 02XX 1	Vessel Kanül *Vessel Cannula*	47798	Steril *Sterile*	ISO 80369-7 (2016)	Kural 7 Rule 7
41	330 03XX 1	Kardiyopleji Adaptörü *Cardioplegia Adapter*	58824	Steril *Sterile*	NA	Kural 2 Rule 2
42	330 05XX 1 330 0XXX 1	Turnike set *Tourniquet set*	36082	Steril *Sterile*	NA	Kural 7 Rule 7

43	332 XXXX 1	Aortik Punch *Aortic Punch*	47914	Steril *Sterile*	NA	Kural 6 Rule 6
44	135 XXXX 1 138 XXXX 1 340 XXXX 1 341 XXXX 1	Anjiografik Opak Madde Verme Seti *Angiographic Kit*	16545	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
45	420 XX01 1 042 000X 1	Yumuşak Dren *Soft Drain*	11305	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
46	421 0001 1	Torasentez Seti *Thoracentesis Set*	10817	Steril *Sterile*	ISO 80369-7 (2016) EN ISO 8669-2 (1996)	Kural 6 Rule 6
47	425 0001 1 042 0001 1	Göğüs Drenaj Torbası *Pleural Drainage Bag*	10817	Steril *Sterile*	NA	Kural 7 Rule 7
48	440 4001 1	Arteriyal Filtre Seti *Arterial Filter Set*	33309	Steril *Sterile*	NA	Kural 2 Rule 2
49	550 00XX 1 551 00XX 1 055 XXXX 1	Endotrakeal Tüp (Balonlu/Balonsuz) *Endotracheal Tube (Cuffed/Uncuffed)*	46967	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
50	550 8XXX 1 551 8XXX 1	RAE Endotrakeal Tüp (Balonlu/Balonsuz) *RAE Endotracheal Tube (Cuffed/Uncuffed)*	46967	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
51	550 7XXX 1 551 7XXX 1 055 XXXX 1 095 22XX 1	Spiralli Endotrakeal Tüp (Balonlu/Balonsuz) *Reinforced Endotracheal Tube (Cuffed/Uncuffed)*	46569	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
52	551 1XXX 1	Endotrakeal Tüp (Balonlu, XX mm Stile) Endotracheal Tube *(Cuffed with XX mm Stylet)*	46967	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
53	551 20XX 1	Spiralli Endotrakeal Tüp (Balonlu, XX mm Stile) *Reinforced Endotracheal Tube (Cuffed with XX mm Stylet)*	46569	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
54	555 0XXX 1 556 0XXX 1 055 XXXX 1 095 22XX 1	Trakeostomi Tüp *Tracheostomy Tube*	35404	Steril *Sterile*	EN 1282-2 (2005- A1:2009) EN ISO 5366 (2016)	Kural 5 Rule 5
55	560 200X 1 560 2001 1	Nasal Oksijen Kanülü *Nasal Oxygen Cannula*	35201	Steril *Sterile*	NA	Kural 2 Rule 2
56	563 XXXX 1 056 XXXX 1	Oksijen Kateteri *Oxygen Catheter*	35203	Steril *Sterile*	NA	Kural 2 Rule 2

57	565 XXXX 1 056 XXXX 1	Oksijen Bağlantı Hortumu *Oxygen Connecting Tube*	12875	Steril *Sterile*	EN 1617 (1997) ISO 20697 (2018)	Kural 2 Rule 2
58	573 0X7X 1 057 0X7X 1	Gaz Örnekleme Hattı *Gas Sampling Line*	45566	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
59	723 XX70 1 726 XX70 1 724 XXXX 1 072 XXXX 1	Cerrahi Örme Bant *Surgical Braided Tape*	36082	Steril *Sterile*	NA	Kural 7 Rule 7
60	760 XXXX 1 076 XXXX 1	Üç Yollu Musluk *Three Way Stopcock*	32172	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
61	765 XXXX 1 076 XXXX 1	Manifold *Manifold*	32172	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
62	790 XX01 1 079 XXXX 1	Redon Dren *Redon Drain*	11305	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
63	330 0450 1	Koroner Arter Retraksiyon Klipsi-3.0mm *Coronary Artery Retraction Clips-3.0mm*	47991	Steril *Sterile*	NA	Kural 6 Rule 6
64	330 0451 1	Koroner Arter Retraksiyon Klipsi-5.0mm Coronary Artery Retraction Clip-5.0mm	47991	Steril *Sterile*	NA	Kural 6 Rule 6

Sınıf Im Ürünler / *Class Im Products*

Sıra No	**Ürün Referansı**	**Ürün Adı**	**GMDN Kodu**	**Sterilite Durumu**	**İlgili Ürün Standardı**	**Ürün Risk Kuralı**
No	*Product Reference*	*Product Name*	GMDN Code	Sterility State	*Related Product Standard*	Device Risk Rule
1	186 XXXX 2	B-Spiro Nefes Egzersiz Cihazı *B-Spiro Volumetric Exerciser*	31266	Non-Steril Non-Sterile	NA	Kural 5 Rule 5

Sınıf Is Ürünler / *Class Is Products*

Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	100 XXXX 1 101 XXXX 1 102 XXXX 1 103 XXXX 1 010 XXXX 1	I.V. İnfüzyon Seti *I. V. Infusion Set*	58977	Steril *Sterile*	ISO 8536-4 (2019) EN ISO 8536-8 (2015)	Kural 2 Rule 2

2	106 XXXX 1 107 000X 1	Damla Ayar Seti *Flow Regulator*	36244	Steril *Sterile*	ISO 80369-7 (2016) ISO 8536-4 (2019)	Kural 2 Rule 2
3	106 000X 1 107 000X 1 010 05XX 1	Infüzyon Seti-Damla Ayarlı *I.V. Infusion Set w/Flowmeter*	58977	Steril *Sterile*	ISO 8536-4 (2019) ISO 8536-8 (2015)	Kural 2 Rule 2
4	120 XXXX 1 121 XXXX 1 122 XXXX 1 012 XXXX 1	Uzatma Hatları Extention Lines	12170	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
5	125 0005 1 125 0001 1 012 XXXX 1	Stoper / İnstoper *Stopper/ Instopper*	31667	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
6	125 0007 1 012 XXXX 1	Kombi Stoper *Combi stopper*	31667	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
7	125 0010 1 012 XXXX 1	Transfer Set	41222	Steril *Sterile*	NA	Kural 1 Rule 1
8	125 10XX 1 130 XXXX 1 131 XXXX 1 012 XXXX 1	B Safe	42727	Steril *Sterile*	ISO 80369-1 (2018) ISO 80369-7 (2016) ISO 80369-20 (2015)	Kural 2 Rule 2
9	131 00XX 1 132 00XX 1 133 XXXX 1 124 XXXX 1 013 XXXX 1	B Safe Valfli Uzatma-İkili/Üçlü/T-Konnektörlü *Extension Line w/B-Safe Duo/Triple/T-Connector*	12170	Steril *Sterile*	ISO 80369-1 (2018) ISO 80369-7 (2016) ISO 80369-20 (2015)	Kural 2 Rule 2
10	135 XXXX 1 138 XXXX 1 013 80XX 1	Basınca Dayanıklı Uzatma Hatları *Pressure Extention Lines*	35529	Steril *Sterile*	ISO 80369-7 (2016) ISO 8536-9 (2015)	Kural 2 Rule 2
11	222 XXXX 1 223 XXXX 1 226 XXXX 1 022 XXXX 1	İdrar Torbası *Urine Collection Bag*	58921 58922	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
12	022 XXXX 1	Bacak İdrar Torbası *Leg Bag*	58924	Steril *Sterile*	NA	Kural 1 Rule 1
13	228 XXXX 1 022 XXXX 1	Lavman Seti Lavman Torba *Enema Set* *Enema Bag*	35050	Steril *Sterile*	NA	Kural 5 Rule 5
14	230 0001 1 023 0001 1	Göbek Kordon Klempi *Umbilical Cord Clamp*	43998	Steril *Sterile*	TS 6782: 1989 (T1:1994)	Kural 1 Rule 1
15	235 0001 1 023 0001 1	Konik Konnektör *Conical Connector*	44545	Steril *Sterile*	NA	Kural 1 Rule 1

16	236 XXXX 1 023 0001 1	Hortum Konnektörü *Tubing Connector*	44545	Steril *Sterile*	NA	Kural 2 Rule 2
17	236 1001 1	Mekonyum Aspiratör Konnektörü *Meconium Aspirator Connector*	35917	Steril *Sterile*	NA	Kural 2 Rule 2
18	238 0001 1 238 0011 1 023 XXXX 1	Kateter Tıkacı *Spigot*	31667	Steril *Sterile*	NA	Kural 1 Rule 1
19	240 0001 1 024 0001 1	Kapkon Konnektör *Kapkon Connector*	44545	Steril *Sterile*	NA	Kural 1 Rule 1
20	430 XXXX 1 043 XXX1 1	TUR Set	46102	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
21	450 XXX1 1 045 XXXX 1	Artroskopi Set *Arthroscopy Set*	46102	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
22	550 0001 1 550 0002 1 550 0003 1 055 XXXX 1	Entübasyon Stilet *Entubation Stylet*	37469	Steril *Sterile*	NA	Kural 5 Rule 5
23	595 10XX 1	Vajinal Spekulum *Vaginal Specula*	37468	Steril *Sterile*	TS 5537:1988 T3: 2003	Kural 5 Rule 5
24	750 XXXX 1 075 XXXX 1	Düz Konnektör *Straight Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
25	751 XXXX 1 075 XXXX 1	Düz Luer Konnektör *Straight Luer Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
26	754 XXXX 1 075 XXXX 1	Y Konnektör *Y Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
27	755 XXXX 1 075 XXXX 1	Y Luer Konnektör *Y Luer Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
28	900 XXXX 1 095 90XX 1 090 XXXX 1	Guedel Havayolu *Guedel Airway*	42424	Steril *Sterile*	EN ISO 5364 (2016)	Kural 2 Rule 2
29	034 XXXX 1	Kontrol Şırıngası *Control Syringe*	15286	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2

Sınıf Is-Im Ürünler / *Class Is & Im Products*

Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	010 XXXX 1 105 XXXX 1 095 11XX 1	I.V. Infüzyon Seti-Büretli *I.V. Infusion Set-w/Burette*	12159	Steril *Sterile*	EN ISO 8536-5 (2013) ISO 80369-7 (2016)	Kural 2 Rule 2

2	011 XXXX 1 110 0001 1	C. V. P. SET *Central Venous Pressure Monitoring Set*	35529	Steril *Sterile*	ISO 8536-4 (2019) ISO 80369-7 (2016)	Kural 2 Rule 2
3	017 XXXX 1 175 XXXX 1	BPDS- Göğüs drenaj seti *Pleural Drainage Set*	10817	Steril *Sterile*	ISO 20697 (2018)	Kural 1 Rule 1
4	017 XXXX 1 176 200X 1	BTDS –Toraks drenaj seti *Thoracic Drainage Set*	10817	Steril *Sterile*	ISO 20697 (2018)	Kural 1 Rule 1
5	227 XXXX 1 022 XXXX 1	Ürimetre *Urimeter*	32072	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
6	022 7XXX 1 227 10XX 1	Urimetre İdrar Torbalı *Urimeter w/Urine Bag*	32072	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
7	027 1023 1	Ürimetre 500 Plus - İğnesiz Num. Portlu-Çek Valf *Urimeter 500 Plus-Needleless Sample-Check Valve*	32072	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
8	022 7404 1	Urimeter 500 Plus Safety	32072	Steril Sterile	EN ISO 8669-2 (1996)	Kural 1 Rule 1

Açıklama: XXXX ürünün farklı uzunluk, ölçü gibi farklılıklarını ifade etmektedir.
Explanation:XXXX means different length, sizes etc. product.
NA: İlgili ürün standardı bulunmamaktadır./ **There is no related product standard.**

ONAY / APPROVAL	
Yayın Yeri ve İmza Tarihi **Signature Date and Place of Issue**	**TURKEY/ 07.10.2022**
Yetkili kişinin adı, ünvanı, imzası ve firma kaşesi **Name, title, signature of authorized person with company cachet**	
Kalite Güvence Uzmanı **Quality Assurance Specialist**	Kalite ve Regülasyon Yöneticisi **Quailty and Regulatory Exercutive**
Selda ÇAKMAK	Aysel YILDIRIM
Selda ÇAKMAK Kalite Güvence Uzmanı *Quality Assurance Specialist*	Aysel YILDIRIM Kalite ve Regülasyon Yöneticisi *Quality and Regulatory Executive*

Manufacturer:

R-Vent Medikal Uretim A.S.
A: Yazibasi Mah. Balkan Cad.
İztipsan Apt. No:33/1
Torbali, Izmir, Turkey

Document id. and Rev. Number:

DOC01-00

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC NB No: 2195

Product Name	: BREATHING, ANESTHESIA, CPAP, BPAP, IPPB CIRCUITS, GAS SAMPLING LINES
Product Model Number(s)	: R-Vent, See below list for code
Description	: Disposable devices used to conduct medical gases from the anaesthesia system to the patient. The breathing system may additionally connect between the patient, ventilator, circle absorber and monitor connections.
GMDN Code(s)	: 37704, 37706, 45566

The declaration covers the following codes at Annex 1

Sterile	: Sterile / Non-sterile
Classification / Rule ((acc. to MDD – Annex IX)	: Class II a / Rule 2
Conformity Assessment Route	: Annex V, Article 3
Declaration	:

1. R-Vent Medikal Uretim A.S.. declares that the above products to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC of 14 June 1993, concerning medical devices, which allows theirs free distribution, sale and circulation in EEC.

2. As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate Number: 2195-MED-1816401
QMS Certificate Number: 31816401
Notified Body: Szutest Uygunluk Değerlendirme (id. # 2195)
Notified Body Adres: Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul

All supporting documentation is retained at the manufacturer's premises
Signature on behalf of R-Vent Medikal Uretim A.S..

Applied Standarts:
93/42/EEC Medical Device Directive, TS EN ISO 5356-1:2015, TS EN ISO 11135:2014, TS EN ISO 10993-1:2021, TS EN ISO 10993-5:2010, TS EN ISO 10993-10:2014, TS EN ISO 10993-12:2021, TS EN ISO 5362:2019, TS EN ISO 5367:2015, ISO 13485:2016, TS EN ISO 15223-1:2021 , TS EN ISO 20417:2021, TS EN ISO 14644-1:2016, TS EN ISO 11607-1: 2020, TS EN ISO 14971:2020, TS EN ISO 24971:2021, TS EN ISO 10993-7:2010, TS EN ISO 10993-14: 2010, TS EN ISO 10993-11: 2018, TS EN ISO 11737-1:2018, TS EN ISO 11737-2 : 2020, TS EN 62366-1: 2015

Signature:

Aybüke Elif US
QA Responsible

R VENT MEDİKAL ÜRETİM A.Ş.
Yazıbaşı Mah. Balkan Cad. İztipsan Apt. No:33
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Tel:(0232) 853 97 26 Fax:(0232) 853 97 30
Torbalı V.D 734 081 2763
Mersis No:0734081276300012

Annex 1

This conformity Covers all the circuit codes in R-Vent's Product Range

ABCDEFGH-I

1 Range of A is between 0-9
2 Range of B is between 0-9
3 Range of C is between 0-9 except 7 and 8
4 Range of D is between 0-2
5 Range of E is between 0-9
6 Range of F is between 0-9 except 8
7 Range of G is between 0-9
8 Range of H is between 0-6
9 Range of I is between 0-9

For more information see R-Vent Code key.

3114	3MT GAS SAMPLING LINE (MALE-MALE CONNECTOR)
3104	3MT GAS SAMPLING LINE (MALE-FEMALE CONNECTOR)
3115	3 MT GAS SAMPLING LINE (MALE-MALE CONNECTOR)
2114	2MT GAS SAMPLING LINE (MALE-MALE CONNECTOR)
2104	2 MT GAS SAMPLING LINES (MALE-FEMALE CONNECTOR)
2115	2 MT GAS SAMPLING LINE (MALE-MALE CONNECTOR)
3104F	3 MT GAS SAMPLING LINE WITH FILTER (MALE-FEMALE CONNECTOR)
3114F	3MT GAS SAMPLING LINE WITH FILTER(MALE-MALE CONNECTOR)

Manufacturer:

R-Vent Medikal Uretim A.S.
A: Yazibasi Mah. Balkan Cad.
İztipsan Apt. No:33/1
Torbali, Izmir, Turkey

Document id. and Rev. Number:

DOC02-00

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

NB No: 2195

Product Name	: CLOSED SUCTION SYSTEM
Product Model Number(s)	: R-Vent, See below list for code
Description	The closed suction set applies in respiratory system disease, general anesthesia surgery and emergency salvage therapy. Closed Suction Set is also a device used for avoiding airborne or aerolized contamination and the possibility of clinician to contact with secretions. The closed suction set will connect the control valve and the tube of the aspirator when doctor use it.
GMDN code(s)	: 10749

The declaration covers the codes at Annex 1

Sterile	: Sterile
Classification / Rule ((acc. to MDD – Annex IX)	: Class II a / Rule 5
Conformity Assessment Route	: Annex V, Article 3

Declaration

1. R-Vent Medikal Uretim A.S. declares that the above products to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC of 14 June 1993, concerning medical devices, which allows theirs free distribution, sale and circulation in EEC.

2. As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate Number: 2195-MED-1816401
QSys Certificate Number: 31816401
Notified Body: Szutest Uygunluk Değerlendirme (id. # 2195)
Notified Body Adres: Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul

All supporting documentation is retained at the manufacturer's premises

Signature on behalf of R-Vent Medikal Uretim A.S.

Applied Standarts:
93/42/EEC Medical Device Directive, TS EN ISO 5356-1:2015, ISO 10993-1:2021, ISO 10993-5:2010, ISO 10993-11:2018, TS EN ISO 10993-12:2021, TS EN ISO 5367:2015, ISO 13485:2016, TS EN ISO 15223-1:2021 , TS EN ISO 20417: 2021 , TS EN ISO 14644-1:2016, TS EN ISO 14971:2020 , TS EN ISO 24971:2021, TS EN ISO 10993-14:2010 , TS EN 62366-1: 2015 , TS EN ISO 10651-4: 2010 , TS EN 13544-2+A1: 2010 , TS EN ISO 27427: 2019, ISO 8836:2021

Signature:

Aybüke Elif US
QA Responsible

R VENT MEDİKAL ÜRETİM A.Ş.
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Torbalı V.D 734 081 2763
Mersis No:0734081276300012

Annex 1

Product(s) included within the scope of this Declaration of Conformity :

24Hr	72Hr	72Hr with Tracheostomy
24050	72050	72101
24060	72060	72121
24070	72070	72141
24080	72080	72161
24100	72100	
24120	72100-1 (With Catheter Mount)	
24140	72120	
24160	72120-1 (With Catheter Mount)	
	72140	
	72140-1 (With Catheter Mount)	
	72160	

Manufacturer:

R-Vent Medikal Uretim A.S.
A: Yazibasi Mah. Balkan Cad.
İztipsan Apt. No:33/1
Torbali, Izmir, Turkey

Document id. and Rev. Number:

DOC04-00

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

NB No: 2195

Product Name	: BREATHING FILTERS
Product Model Number(s)	: R-Vent, See below list for code
Description	: Disposable devices used to conduct medical gases from the anesthesia system to the patient. Breathing filters are barriers that separates patient environment from outside. This product filters the air inhaled and exhaled by the patient. By this way it provides microbiological protection for both patient and appliers in the hospitals.
GMDN Code(s)	: 60837,37597

The declaration covers the following codes at Annex 1

Sterile	: Both sterile and non-sterile
Classification / Rule ((acc. to MDD – Annex IX)	: Class II a / Rule 3
Conformity Assessment Route	: Annex V, Article 3
Declaration	:

1. R-Vent Medikal Uretim A.S.. declares that the above products to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC of 14 June 1993, concerning medical devices, which allows theirs free distribution, sale and circulation in EEC.

2. As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate Number: 2195-MED-1816401
QMS Certificate Number: 31816401
Notified Body: Szutest Uygunluk Değerlendirme (id. # 2195)
Notified Body Adres: Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul

All supporting documentation is retained at the manufacturer's premises
Signature on behalf of R-Vent Medikal Uretim A.S..

Applied Standarts:
93/42/EEC Medical Device Directive, TS EN ISO 5356-1:2015, TS EN ISO 11135:2014, TS EN ISO 10993-1:2021, TS EN ISO 10993-5:2010, TS EN ISO 10993-10:2014, TS EN ISO 10993-12:2021, TS EN ISO 5362:2019, TS EN ISO 5367:2015, ISO 13485:2016, TS EN ISO 15223-1:2021, TS EN ISO 20417:2021, TS EN ISO 14644-1:2016, TS EN ISO 11607-1: 2020, TS EN ISO 14971:2020, TS EN ISO 24971:2021, TS EN ISO 10993-7:2010, TS EN ISO 10993-14: 2010, TS EN ISO 10993-11: 2018, TS EN ISO 11737-1:2018, TS EN ISO 11737-2 : 2020, TS EN 62366-1: 2015, TS EN ISO 9360-1:2010, TS EN ISO 9360-2:2010, ISO 23328-1: 2011, ISO 23328-2: 2011, TS EN ISO 80369-7:2021

Signature:

Aybüke Elif US
QA Responsible

R VENT MEDİKAL ÜRETİM A.Ş.
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Torbalı V.D 734 081 2763
Mersis No:0734081276300012

Annex 1

Product(s) included within the scope of the Declaration of Conformity :

Product Code	Product Name
40910	BACTERIAL/VIRAL FILTER WITH LUER LOCK CAP
40911	BACTERIAL/VIRAL FILTER WITH LUER LOCK CAP WITH ELBOW
40910S	BACTERIAL/VIRAL FILTER WITH LUER LOCK CAP (STERILE EO)
40911S	BACTERIAL/VIRAL FILTER WITH LUER LOCK CAP WITH ELBOW (STERILE EO)
40210	BACTERIAL/VIRAL FILTER MINI WITH LUER LOCK CAP
40211	BACTERIAL/VIRAL FILTER MINI WITH LUER LOCK CAP WITH ELBOW
40210S	BACTERIAL/VIRAL FILTER MINI WITH LUER LOCK CAP (STERILE EO)
40211S	BACTERIAL/VIRAL FILTER MINI WITH LUER LOCK CAP WITH ELBOW (STERILE EO)
40410	BACTERIAL/VIRAL HME FILTER MINI WITH LUER LOCK CAP
40411	BACTERIAL/VIRAL HME FILTER MINI WITH LUER LOCK CAP WITH ELBOW
40410S	BACTERIAL/VIRAL HME FILTER MINI WITH LUER LOCK CAP (STERILE EO)
40411S	BACTERIAL/VIRAL HME FILTER MINI WITH LUER LOCK CAP WITH ELBOW (STERILE EO)
40500	TRACHEOSTOMY FILTER
40500S	TRACHEOSTOMY FILTER (STERILE EO)
40600	TRACHEOSTOMY FILTER WITH OXYGEN TUBING
40600S	TRACHEOSTOMY FILTER WITH OXYGEN TUBING (STERILE EO)
40820	BACTERIAL/VIRAL HME FILTER WITH SOFT CAP
40821	BACTERIAL/VIRAL HME FILTER WITH SOFT CAP WITH ELBOW
40820S	BACTERIAL/VIRAL HME FILTER WITH SOFT CAP (STERILE EO)
40821S	BACTERIAL/VIRAL HME FILTER WITH SOFT CAP WITH ELBOW (STERILE EO)
40810	BACTERIAL/VIRAL HME FILTER WITH LUER LOCK CAP
40811	BACTERIAL/VIRAL HME FILTER WITH LUER LOCK CAP WITH ELBOW
40810S	BACTERIAL/VIRAL HME FILTER WITH LUER LOCK CAP (STERILE EO)
40811S	BACTERIAL/VIRAL HME FILTER WITH LUER LOCK CAP WITH ELBOW (STERILE EO)
40920	BACTERIAL/VIRAL FILTER WITH SOFT CAP
40921	BACTERIAL/VIRAL FILTER WITH SOFT CAP WITH ELBOW
40920S	BACTERIAL/VIRAL FILTER WITH SOFT CAP (STERILE EO)
40921S	BACTERIAL/VIRAL FILTER WITH SOFT CAP WITH ELBOW (STERILE EO)
41100	TRACHEOSTOMY FILTER WITH HME PAPER
41100S	TRACHEOSTOMY FILTER WITH HME PAPER (STERILE EO)
41200	TRACHEOSTOMY FILTER WITH HME PAPER OXYGEN TUBING
41200S	TRACHEOSTOMY FILTER WITH HME PAPER OXYGEN TUBING (STERIL EO)
40100	TRACHEOSTOMY FILTER HME
40100S	TRACHEOSTOMY FILTER HME (STERIL EO)
40320	BACTERIAL/VIRAL HEPA FILTER
40320S	BACTERIAL/VIRAL HEPA FILTER (STERILE EO)
41520	BACTERIAL/VIRAL HEPA HME FILTER
41520S	BACTERIAL/VIRAL HEPA HME FILTER (STERILE EO)
40900	BACTERIAL /VIRAL FILTER WITHOUT PORT
40900S	BACTERIAL /VIRAL FILTER WITHOUT PORT(STERILE EO)
41600	TRACHEOSTOMY FILTER WITHOUT PORT
41600S	TRACHEOSTOMY FILTER WITHOUT PORT (STERILE EO)

Manufacturer:

R-Vent Medikal Uretim A.S.
A: Yazibasi Mah. Balkan Cad.
İztipsan Apt. No:33/1
Torbali, Izmir, Turkey

Document id. and Rev. Number:

DOC05-00

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

NB No: 2195

Product Name	: CATHETER MOUNT
Product Model Number(s)	: R-Vent, See below list for codes.
Description	: A device used to connect a breathing circuit to a tracheal tube, face mask, or other breathing circuit component. This device may be used to adapt breathing tubes from adult to paediatric size because it is designed with connections whose outer and inner dimensions are standardized by ISO to 22 mm and 15 mm.
GMDN Code(s)	: 42476
The declaration covers codes at Annex 1	
Sterile	: Sterile/ Non-sterile
Classification / Rule ((acc. to MDD – Annex IX)	: Class II a / Rule 2
Conformity Assessment Route	: Annex V, Article 3
Declaration	:

1. R-Vent Medikal Uretim A.S. declares that the above products to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC of 14 June 1993, concerning medical devices, which allows theirs free distribution, sale and circulation in EEC.

2. As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate Number: 2195-MED-1816401

QMS Certificate Number: 31816401

Notified Body: Szutest Uygunluk Değerlendirme (id. # 2195)

Notified Body Adres: Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul

All supporting documentation is retained at the manufacturer's premises

Signature on behalf of R-Vent Medikal Uretim A.S.

Applied Standards:

93/42/EEC Medical Device Directive, TS EN ISO 5356-1:2015, TS EN ISO 11135:2014, TS EN ISO 10993-1:2021, TS EN ISO 10993-5:2010, TS EN ISO 10993-10:2014, TS EN ISO 10993-12:2021 , TS EN ISO 5362:2019, TS EN ISO 5367:2015, ISO 13485:2016, TS EN ISO 15223-1:2021, TS EN ISO 20417:2021, TS EN ISO 14644-1:2016, TS EN ISO 11607-1: 2020, TS EN ISO 14971:2020, TS EN ISO 24971:2021, TS EN ISO 10993-7:2010, TS EN ISO 10993-14: 2010, TS EN ISO 10993-11: 2018, TS EN ISO 11737-1:2018, TS EN ISO 11737-2 : 2020, TS EN 62366-1: 2015

Signature:

Aybüke Elif US
QA Responsible

R VENT MEDİKAL ÜRETİM A.Ş.
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Torbalı V.D 734 081 2763
Mersis No:0734081276300012

Annex 1

Product(s) included within the scope of this Declaration of Conformity :

Code	Name
314380	Catheter Mount
317380	Catheter Mount
312300	Catheter Mount
316300	Catheter Mount
313300	Catheter Mount
317300	Catheter Mount
314300	Catheter Mount
367300	Catheter Mount
366300	Catheter Mount
300000	Catheter Mount
322300	Catheter Mount
326300	Catheter Mount
323300	Catheter Mount
316400	Catheter Mount
316100	Catheter Mount
327300	Catheter Mount
312300S	Catheter Mount
316300S	Catheter Mount
322300S	Catheter Mount
326300S	Catheter Mount
313300S	Catheter Mount
317300S	Catheter Mount
323300S	Catheter Mount
327300S	Catheter Mount
367300S	Catheter Mount
366300S	Catheter Mount
317340	Catheter Mount
317340S	Catheter Mount
31000	Catheter Mount
31000S	Catheter Mount
316400S	Catheter Mount
377300	Catheter Mount
377300S	Catheter Mount
316100S	Catheter Mount
376300	Catheter Mount
376300S	Catheter Mount
363300	Catheter Mount
363300S	Catheter Mount
367340	Catheter Mount
367340S	Catheter Mount
366340	Catheter Mount
366340S	Catheter Mount
316340	Catheter Mount
316340S	Catheter Mount

Manufacturer:

R-Vent Medikal Uretim A.S.
A: Yazibasi Mah. Balkan Cad.
İztipsan Apt. No:33/1
Torbali, Izmir, Turkey

Document id. and Rev. Number:

DOC06-00

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

NB No: 2195

Product Name	: Disposable BVM Resuscitator
Product Model Number(s)	: R-Vent, See below list for code
Description	: It is applicable for pulmonary resuscitation and assisting for manual respiration, it can be used singly. It is also can be used by connecting with supplying oxygen of compressed source, the patients has sufficient oxygen supply improve the hypoxia
GMDN Code(s)	: 36086

The declaration covers the following codes at Annex 1

Sterile	: Non-sterile
Classification / Rule ((acc. to MDD – Annex IX)	: Class II a / Rule 2
Conformity Assessment Route	: Annex V, Article 3
Declaration	:

1. R-Vent Medikal Uretim A.S.. declares that the above products to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC of 14 June 1993, concerning medical devices, which allows theirs free distribution, sale and circulation in EEC.

2. As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate Number: 2195-MED-1816401
QMS Certificate Number: 31816401
Notified Body: Szutest Uygunluk Değerlendirme (id. # 2195)
Notified Body Adres: Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul

All supporting documentation is retained at the manufacturer's premises
Signature on behalf of R-Vent Medikal Uretim A.S..
Applied Standarts:
93/42/EEC Medical Device Directive, TS EN ISO 5356-1:2015, TS EN ISO 11135:2014, TS EN ISO 10993-1:2021, TS EN ISO 10993-5:2010, TS EN ISO 10993-10:2014, TS EN ISO 10993-12:2021, TS EN ISO 5367:2015, ISO 13485:2016, TS EN ISO 15223- 1:2021, TS EN ISO 20417:2021,TS EN ISO 14644-1:2016, TS EN ISO 14971:2020, TS EN ISO 24971:2021, TS EN ISO 10993-14:2010, TS EN 62366-1: 2015, TS EN ISO 10651-4: 2010, TS EN 13544-2+A1: 2010, TS EN ISO 27427: 2019

Signature:

Aybüke Elif US
QA Responsible

R VENT MEDİKAL ÜRETİM A.Ş.
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Torbalı V.D 734 081 2763
Mersis No:0734081276300012

Annex 1

Product(s) included within the scope of the Declaration of Conformity :

Product Code	Product Code
9000	BVM RESUSCITATOR LARGE, MASK,O2 TUBING
9010	BVM RESUSCITATOR MEDIUM, MASK,O2 TUBING
9020	BVM RESUSCITATOR SMALL, MASK, O2 TUBING
9030	BVM RESUSCITATOR LARGE, O2 TUBING
9040	BVM RESUSCITATOR MEDIUM,O2 TUBING
9050	BVM RESUSCITATOR SMALL, O2 TUBING
9060	BVM RESUSCITATOR LARGE, MASK,O2 TUBING, PEEP VALVE
9070	BVM RESUSCITATOR MEDIUM, MASK,O2 TUBING, PEEP VALVE
9080	BVM RESUSCITATOR SMALL, MASK, O2 TUBING, PEEP VALVE
9031	BVM RESUSCITATOR LARGE, MASK,O2 TUBING, MANOMETER
9041	BVM RESUSCITATOR MEDIUM, MASK,O2 TUBING, MANOMETER
9051	BVM RESUSCITATOR SMALL, MASK, O2 TUBING, MANOMETER
9061	BVM RESUSCITATOR LARGE, MASK,O2 TUBING, MANOMETER, PEEP VALVE
9071	BVM RESUSCITATOR MEDIUM, MASK,O2 TUBING, MANOMETER, PEEP VALVE
9081	BVM RESUSCITATOR SMALL, MASK, O2 TUBING, MANOMETER, PEEP VALVE

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producing health for the world

DECLARATION OF CONFORMITY

Manifacturer: DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.
Address: Balıkhisar Mahallesi Köyiçi Serpmeleri No: 795/A Akyurt / Ankara
Brand Name: Dört-A Medical
Product Name: Aspiration Handle Vacuum Controlled / Uncontrolled
Product Code: ***4AYH***
Product Models: **4AYHWV*ASPIRATION HANDLE VACUUM CONTROLLED***
4AYHW-OUTV *ASPIRATION HANDLE VACUUM UNCONTROLLED*

Applicable directives: 93/42/EEC Medical Devices Directives, Annex II Except Clause 4 (Class IIa) Classification: Class IIa, Rule 7, Annex IX
Classification: Class IIa, Rule 7, Annex IX
GMDN No: 35917

Applicable Standards: TS EN ISO 14971:2019, TS EN ISO 24971:2020, ***EN ISO 15223-1:2021***, ISO 9001:2015, ISO 13485:2016, TS EN 20417:2021,TS EN ISO 14644-1:2016, TS EN ISO 14644-2:2016,TS EN ISO 14644-3:2019,TS EN ISO 14644-4:2006, TS EN ISO 14644-5:2006,***TS EN ISO 10993-12:2021***,TS ISO 11135:2014,TS EN ISO 14937:2011,TS ISO 11607-1:2020, TS EN ISO 11607-2:2020,TS EN ISO 11737-2:2020, TS EN ISO 17141:2020,TS EN ISO 10993-3:2015, TS EN ISO 10993-4:2020, TS EN ISO 10993-5:2010, TS EN ISO 10993-7:2010, TS EN ISO 10993-10:2014, TS EN ISO 10993-11:2018, TS EN 20697 : 2018, TS EN 10993-1 : 2020

Certified body: UDEM International Certification Auditing Training Center Industry And Trade Inc. Co.
Certified body address: Mutlukent Mahallesi 2073.Sokak(Eski 93 Sokak) No:10 Çankaya-Ankara-Turkey
Descriptive number: 2292
Certificate No: M.2016.106.7276
First CE mark: 31.07.2012
Certificate Expiry Date: ***27.05.2024***

We DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.declare that above mentioned product is fulfilling all legislation provisions in 93/42/EEC provision. We are conserving all corroborative documents in our own facility.

Place, Issue Date: ***Ankara, 12.01.2022*** Canan ÖKTEM, General Manager
Sign, Stamp

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REVISION HISTORY		
Rev. No:	***Rev. Date***	***Rev. Reason***
00	*08.04.2021*	*First Publising*
01	16.08.2021	Standard dates and document validity period have been updated
02	***12.01.2022***	***Standard dates have been updated.***

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DECLARATION OF CONFORMITY

Manufacturer	:	Medbar Tıbbi Malzemeler Turizm San. ve Tic. A.Ş. 1142 sok. No:35 Fatih Mah. Sarnıç - Izmir / Turkey Phone: +90 232 2816003 Fax: +90 232 2816648
Product(s)	:	Sterile Dry Surgical Hand Brush (Ref:205 03)
Classification	:	Not Medical Device

We hereby declare that above mentioned product is not classified as medical device for European Commission published on July 2014 Manual On Borderlıne And Classificatıon In The Communıty Regulatory Framework For Medıcal Devıces Version 1.16.

Appearance	:	Sterile Dry Single Use Surgical Hand Brush
Shelf Life	:	5 years
Competent Authority	:	Ministery of Health of the Republic of Turkey
Place, Date of Issue	:	Izmir/Turkey - 08.03.2016
Signature	:	General Manager Ü. Ömer Baran

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