

Üretici/ Manufacturer:

Meditera Tıbbi Malzeme Sanayi ve Ticaret A.Ş.
İbni Melek OSB Mh. Tosbi Yol 4 Sk. No: 29
35900 Tire - İzmir - TÜRKİYE

Onaylanmış Kuruluş/ Notified Body: Kiwa Belgelendirme Hizmetleri A.Ş.(1984)

Adres/ Address: İTOSB 9. Cadde No:15 Tepeören Tuzla - İstanbul / TÜRKİYE

Document Id. - Rev. Number - Counter No:

DOC01-02-104

93/42/EEC Medical Cihaz Yönetmeliği
Avrupa Uygunluk Deklarasyonu
European Declaration of Conformity
to the Medical Device Directive, 93/42/EEC



1984

Doküman Kapsamı/Scope of the document**Sterilizasyon Durumu/Sterilization Status****Sınıflandırma - Kural / Classification - Rule**

[MDD - Annex 9] / [acc. to MDD - Annex IX]

Uygunluk Değerlendirme Yolu/ Conformity Assessment Route**Beyanname/ Declaration**

: Steril/Non-Steril Solunum sistemleri ve İnfüzyon sistemleri / Sterile/Non-Sterile Breathing Systems and Infusion Systems

: Steril -Non Steril / Sterile-Non Sterile

: Sınıf II a -Kural 2/ Class II a -Rule 2

: Ek V/Annex V

1. Meditera Tıbbi Malzeme Sanayi ve Ticaret A.Ş. bu beyannamenin ilişkili olduğu yukarıdaki ürünlerin CE İşaretini taşıdığını ve 14 Haziran 1993 tarihli 2007/47/EC Direktif ile değiştirilen 93/42 / EEC sayılı MDD Konsey Direktifinin, EEC de ücretsiz dağıtım, satışa izin veren tıbbi cihazlarla ilgili yürürlükteki şartlarına uygun olduğunu beyan eder.
Meditera Tıbbi Malzeme Sanayi ve Ticaret A.Ş. 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 as amended by directive 2007/47/EC concerning medical devices, which allows their free distribution, sale and circulation in EEC.

2. Yukarıda belirtilen Direktifin gerektirdiği gibi; bu beyanname aşağıdaki dokümanlar tarafından desteklenir:

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

EC Sertifika Numarası-Onaylanmış Kuruluş/EC Certificate No-Notified Body

KYS Sertifika Numarası-Onaylanmış Kuruluş /QSYS Certificate No-Notified Body

:1984-MDD-19-588- Kiwa Belgelendirme Hizmetleri A.Ş.(id. #1984)

: 31826401 - Szutest Uygunluk Değerlendirme A.Ş.

3. Tüm destekleyici belgeler, üreticinin tesislerinde muhafaza edilir.

All supporting documentation is retained at the manufacturer's premise.

4. Bu ürünlerle ilgili olan harmonize standartlar aşağıdadır:

Harmonized standarts which are related to these products are herein below:

EN ISO 13485	EN 556-1
EN ISO 15223-1	EN 15986
EN ISO 10993-1	EN ISO 14155
EN ISO 10993-5	EN ISO 14971
EN ISO 11737-1	EN ISO 11737-2
EN ISO 10993-7	EN ISO 23328-1
EN ISO 9360-1	EN ISO 23328-2
EN ISO 9360-2	EN ISO 11607-2
EN ISO 11135-1	EN ISO 11607-1
EN 1041	

Beyanname aşağıda EK I'de verilen kodları kapsar:

The declaration covers the following codes in Annex I.

Onaylayan/Approved by :

Pozisyon / Position :

Tarih / Date :

İmza /Signature :

Cansu ÖNERCEN

Kalite Güvence Mühendisi/ Quality Assurance Engineer

13.10.2019

ANNEX I

PRODUCT CODE	PRODUCT DESCRIPTION
AL-0005	HUMIDIFICATION CHAMBER AUTOFEED
AL-0410-040/7.V003	JACKSON REEVES CIRCUIT
AL-0512	3MT GAS SAMPLING LINE (MALE-MALE CONNECTOR)
AL-0519	2MT GAS SAMPLING LINE (MALE-MALE CONNECTOR)
AL-07007.V002	0,5 LT BREATHING BAG NEOPRENE (SINGLE PACKED)(ALTECH)
AL-07008.V002	1 LT BREATHING BAG NEOPRENE (SINGLE PACKED)(ALTECH)
AL-07009.V002	2 LT BREATHING BAG NEOPRENE (SINGLE PACKED)(ALTECH)
AL-08002.V005	BACTERIA FILTER WITH LUER LOCK CAP (BIAMEDITEK)
AL-080029.V005	BACTERIA FILTER WITH LUER LOCK CAP (STERILE EO)(BIAMEDITEK)
AL-080049.V004	BACTERIA FILTER MINI (STERILE EO)(BIAMEDITEK)
AL-08006.V005	BACTERIA HME FILTER WITH LUER LOCK CAP (BIAMEDITEK)
AL-080069.V005	BACTERIA HME FILTER (STERILE EO)(BIAMEDITEK)
AL-080089.V004	BACTERIA HME FILTER MINI (STERILE EO)(BIAMEDITEK)
AL-080149.V003	HME FILTER NEONATAL (STERILE EO)(BIAMEDITEK)
AL-08022.V002	BACTERIA HME FILTER WITH LUER LOCK CAP PP (ALTECH)
AL-080229.V002	BACTERIA HME FILTER WITH LUER LOCK CAP PP (STERILE EO)(ALTECH)
AL-080229.V006	BACTERIA HME FILTER PP (STERILE EO)(BIAMEDITEK)
AL-08023.V002	BACTERIA FILTER WITH LUER LOCK CAP PP (ALTECH)
AL-080239.V002	BACTERIA FILTER WITH LUER LOCK CAP PP (STERILE EO) (ALTECH)
AL-080239.V006	BACTERIA FILTER PP (STERILE EO) (BIAMEDITEK)
AL-08025.V004	TRACHEOSTOMY FILTER WITH HME PAPER (BIAMEDITEK)
AL-080259.V003	TRACHEOSTOMY FILTER WITH HME PAPER (STERILE EO) (BIAMEDITEK)
AL-080319.V001	PEDIATRIC BACTERIAL/HME FILTER WITH SOFT CAP(STERILE EO)
AL-080329.V001	NEONATAL BACTERIAL/HME FILTER WITH SOFT CAP(STERILE EO)
AL-09000	ANESTHESIA MASK #0
AL-09001	ANESTHESIA MASK #1
AL-09002	ANESTHESIA MASK #2
AL-09003	ANESTHESIA MASK #3
AL-09004	ANESTHESIA MASK #4
AL-09005	ANESTHESIA MASK #5
AL-09051	PVC FREE ANESTHESIA MASK # 6
AL-09052	PVC FREE ANESTHESIA MASK # 1
AL-09053	PVC FREE ANESTHESIA MASK # 2
AL-09054	PVC FREE ANESTHESIA MASK # 3
AL-09055	PVC FREE ANESTHESIA MASK # 4
AL-09056	PVC FREE ANESTHESIA MASK # 5
AL-10009.V004	CATHETER MOUNT (STERILE EO) (BIAMEDITEK)
AL-1100.V010	BREATHING CIRCUIT
AL-1100.V020	BREATHING CIRCUIT
AL-11009.V002	BREATHING CIRCUIT (STERILE EO)
AL-1101-060.V008	BREATHING CIRCUIT
AL-1101-060.V015	BREATHING CIRCUIT
AL-11100.V002	BREATHING CIRCUIT
AL-11103.V003	BREATHING CIRCUIT
AL-11103-060.V003	BREATHING CIRCUIT
AL-11103-060.V004	BREATHING CIRCUIT
AL-11103-060.V007	BREATHING CIRCUIT
AL-11103-160.V003	BREATHING CIRCUIT
AL-11103-160/5.V001	BREATHING CIRCUIT
AL-1111.V008	BREATHING CIRCUIT
AL-11121-200/9.V001	BREATHING CIRCUIT

AL-11121-206/9.V001	SEPTIFLOW CIRCUIT W/WATERTRAP
AL-1121.V008	BREATHING CIRCUIT
AL-12009.V006	BREATHING CIRCUIT (STERILE EO)
AL-12009.V007	BREATHING CIRCUIT (STERILE EO)
AL-1202-060.V002	BREATHING CIRCUIT
AL-12029-010.V004	BREATHING CIRCUIT (STERILE EO)
AL-12029-060.V001	BREATHING CIRCUIT (STERILE EO)
AL-12029-060.V008	BREATHING CIRCUIT
AL-1212.V006	BREATHING CIRCUIT
AL-12129.V004	BREATHING CIRCUIT (STERILE EO)
AL-12229.V007	BREATHING CIRCUIT (STERILE EO)
AL-12309.V003	CATHETER MOUNT (STERILE EO)(BIAMEDITEK)
AL-13009.V005	BREATHING CIRCUIT (STERILE EO)
AL-1303.V005	BREATHING CIRCUIT
AL-1303-010.V009	BREATHING CIRCUIT
AL-1303-010.V015	BREATHING CIRCUIT
AL-1303-010.V020	BREATHING CIRCUIT
AL-1303-060.V008	BREATHING CIRCUIT
AL-1303-060.V009	BREATHING CIRCUIT
AL-1303-060.V010	BREATHING CIRCUIT
AL-1303-060.V015	BREATHING CIRCUIT
AL-1303-260.V001	BREATHING CIRCUIT
AL-1303-260.V002	BREATHING CIRCUIT
AL-13039-010.V003	BREATHING CIRCUIT (STERILE EO)
AL-13039-060.V001	BREATHING CIRCUIT (STERILE EO)
AL-1400.V007	BREATHING CIRCUIT
AL-15009.V003	BREATHING CIRCUIT (STERILE EO)
AL-1502-060.V001	BREATHING CIRCUIT
AL-15029-060.V001	BREATHING CIRCUIT(STERILE EO)
AL-15229.V004	BREATHING CIRCUIT (STERILE EO)
AL-1603-010.V006	BREATHING CIRCUIT
AL-1603-060.V003	BREATHING CIRCUIT
AL-1603-060.V006	BREATHING CIRCUIT
AL-16300.V006	CATHETER MOUNT (BIAMEDITEK)
AL-16309.V005	CATHETER MOUNT (STERILE EO)(BIAMEDITEK)
AL-1701-060.V003	BREATHING CIRCUIT
AL-17300.V006	CATHETER MOUNT (BIAMEDITEK)
AL-17309.V006	CATHETER MOUNT (STERILE EO)(BIAMEDITEK)
AL-17309.V007	CATHETER MOUNT (CLOSED) (STERILE EO)
AL-1900.V009	MEDI-FLOW CIRCUIT
AL-1903.V005	MEDI-FLOW CIRCUIT
AL-1903-060.V007	MEDI-FLOW CIRCUIT
AL-1903-160.V004	MEDI-FLOW CIRCUIT
AL-19039.V002	MEDI-FLOW CIRCUIT (STERILE EO)
AL-1913-060.V003	BREATHING CIRCUIT
AL-1923-000/9.V001	MEDIFLOW CIRCUIT WITH INSP.& EXP. NEEDLE FREE WATER TRAP
AL-1923-000/9.V002	MEDI-FLOW CIRCUIT
AL-1923-060.V001	MEDI-FLOW CIRCUIT
AL-22209.V001	CATHETER MOUNT (STERILE EO)
AL-22309.V001	CATHETER MOUNT (STERILE EO)(ALTECH)
AL-3210.V004	IPPB CIRCUIT
AL-3210-026.V002	IPPB CIRCUIT
AL-3210-026.V003	IPPB CIRCUIT

AL-32109.V001	IPPB CIRCUIT (STERILE EO)
AL-32109-026.V003	IPPB CIRCUIT
AL-65409.V003	CATHETER MOUNT (STERILE EO)(BIAMEDITEK)
AL-66409.V001	CATHETER MOUNT (STERILE EO)
AL-7100-011.V002	CPAP VENTILATION CIRCUIT
AL-P1903-060.V002	MEDI-FLOW CIRCUIT