

EC CERTIFICATE AT SERTİFİKA

According to Annex V of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz Yönetmeliği Ek V'e göre

Production Quality Assurance System Üretim Kalite Güvencesi

Certificate Number: 2195-MED-1816401

Sertifika Numarası

Manufacturer:
Üretici

R Vent Medikal Üretim A.Ş.
29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, TÜRKİYE

Product(s):
Ürün(ler)

- (1) Sterile and Non-Sterile Breathing Circuit Systems
(1) Steril ve Steril Olmayan Solunum Devre Sistemleri
- (2) Sterile and Non-Sterile Breathing Filters
(2) Steril ve Steril Olmayan Solunum Filtreleri
- (3) Sterile and Non-Sterile Catheter Mounts
(3) Steril ve Steril Olmayan Katater Bağlantıları
- (4) Non-sterile Masks, BVM (Resuscitator), O₂ & Aerosol Therapy Set
(4) Steril Olmayan Maskeler, BVM (Resusitatör), O₂ & Aeresol Terapi Seti
- (5) Sterile Closed Suction System
(5) Steril Kapalı Emiş Sistemi

Reference Report No: MM0687-P004-R01, MM0687-P004-R02, MM0687-P005-R01
Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK V bölüm 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK V, bölüm 4'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyonundaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limitlidir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla limitlidir.

This EC certificate is valid till 2024-05-26.
Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi: 2018-06-13
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Revision Date/ Revizyon Tarihi: 2020-06-26



Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

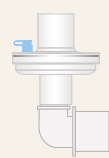
FILTERS



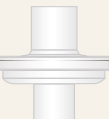
Bacterial-Viral Filters

- Transparent, easy to see the surface
- High efficiency with low resistance electrostatic filters
- Effective to prevent microbial cross contamination
- Remarkably efficient heat and moisture exchangers
- 15 mm/22 mm connectors conforming to ISO Standards
- Retainable cap
- Inspected and approved by third party experts

Bacterial-Viral Filter 	Code	40920
	Sterile Code	40920S
	Qty/Box	50
	Tidal Volume(ml)	150-1500
	Dead Space(ml)	33
	Bacterial-Viral Efficiency	>99,999%
	Viral Efficiency	>99,99%
	Resistance to Flow	30 lt/min 8 mm H ₂ O 60 lt/min 17 mm H ₂ O 90 lt/min 27 mm H ₂ O
	Weight (gr)	17,2
	Fittings	22F-15M/22M-15F

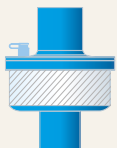
Bacterial-Viral Filter Angled 	Code	40921
	Sterile Code	40921S
	Qty/Box	50
	Tidal Volume(ml)	150-1500
	Dead Space(ml)	36
	Bacterial-Viral Efficiency	>99,999%
	Viral Efficiency	>99,99%
	Resistance to Flow	30 lt/min 8 mm H ₂ O 60 lt/min 17 mm H ₂ O 90 lt/min 27 mm H ₂ O
	Weight (gr)	22,7
	Fittings	22F-15M/22M-15F

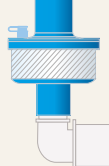
Bacterial-Viral Filter without port 	Code	40900
	Qty/Box	50
	Tidal Volume(ml)	150-1500
	Dead Space(ml)	33
	Bacterial-Viral Efficiency	>99,999%
	Viral Efficiency	>99,99%
	Resistance to Flow	30 lt/min 8 mm H ₂ O 60 lt/min 17 mm H ₂ O 90 lt/min 27 mm H ₂ O
	Weight (gr)	17,2
	Fittings	22F-15M/22M-15F

Bacterial-Viral Filter without port sterile 	Code	40900S
	Qty/Box	50
	Tidal Volume(ml)	150-1500
	Dead Space(ml)	33
	Bacterial-Viral Efficiency	>99,999%
	Viral Efficiency	>99,99%
	Resistance to Flow	30 lt/min 8 mm H ₂ O 60 lt/min 17 mm H ₂ O 90 lt/min 27 mm H ₂ O
	Weight (gr)	17,2
	Fittings	22F-15M/22M-15F

Bacterial-Viral HME Filters

- Transparent
- Low dead space
- Gas sampling port available
- Straight and angled choices
- Low resistance
- Latex-free
- Inspected and approved by third party experts

Bacterial-Viral HME Filter with paper HME 	Code	40820
	Sterile Code	40820S
	Qty/Box	45
	Tidal Volume(ml)	150-1500
	Dead Space(ml)	53
	Bacterial-Viral Efficiency	>99,999%
	Viral Efficiency	>99,99%
	Resistance to Flow	30 lt/min 10 mm H ₂ O 60 lt/min 22 mm H ₂ O 90 lt/min 36 mm H ₂ O
	Weight (gr)	26,2
	Fittings	22F-15M/22M-15F
	Humidification efficiency	37,3 mg/l H ₂ O (500 ml tid. vol)

Bacterial-Viral HME Filter Angled with paper HME 	Code	40821
	Sterile Code	40821S
	Qty/Box	45
	Tidal Volume(ml)	150-1500
	Dead Space(ml)	55
	Bacterial-Viral Efficiency	>99,999%
	Viral Efficiency	>99,99%
	Resistance to Flow	30 lt/min 10 mm H ₂ O 60 lt/min 22 mm H ₂ O 90 lt/min 36 mm H ₂ O
	Weight (gr)	31,7
	Fittings	22F-15M/22M-15F
	Humidification efficiency	37,3 mg/l H ₂ O (500 ml tid. vol)



• HEPA Filters (Mechanical Filters)

- Protects patients airways effectively from exogenous microbial loads
- Reduces the risk of extrinsic colonization and infection
- Prevents any cross-contamination between patient and machine
- Indicated for use with patients whose upper airways are being bypassed by an artificial tracheal airway or receiving artificial ventilator support

Adult HEPA Filter 	Code	40320
	Sterile Code	40320S
	Qty/Box	40
	Tidal Volume(ml)	200-1500
	Dead Space(ml)	52
	Filtration Efficiency	BFE 99,999%; VFE 99,999%
	Resistance to Flow	30 lt/min 156 Pa 60 lt/min 326 Pa 90 lt/min 508 Pa
	Weight (gr)	40
	Fittings	22F-15M/22M-15F

Adult HEPA Filter with HME 	Code	41520
	Sterile Code	41520S
	Qty/Box	40
	Tidal Volume(ml)	200-1500
	Dead Space(ml)	46
	Filtration Efficiency	BFE 99,999%; VFE 99,999%
	Humidification Efficiency	32,2mg/l H ₂ O (500ml. tid. vol.)
	Resistance to Flow	30 lt/min 129 Pa 60 lt/min 305 Pa 90 lt/min 542 Pa
	Weight (gr)	28,4
	Fittings	22F-15M/22M-15F

• Mini Filters

- Optimal filtration performance
- Flat ergonomic design
- Small and light weight
- Gas sampling port
- Straight and angled version
- Latex free
- Inspected and approved by third party experts

Bacterial-Viral HME Pediatric Filter with paper HME 	Code	40410
	Sterile Code	40410S
	Qty/Box	75
	Tidal Volume(ml)	150-300
	Dead Space(ml)	12
	Filtration Efficiency	BFE 99,999%; VFE 99,9%
	Humidification Efficiency	33 mg/l H ₂ O (250 ml. tid. vol.)
	Resistance to Flow	30 lt/min 13mm H ₂ O 60 lt/min 33mm H ₂ O 90 lt/min 55mm H ₂ O
	Weight (gr)	13,5
	Fittings	22F-15M/22M-15F

Bacterial-Viral HME Pediatric Filter Angled with paper HME 	Code	40411
	Sterile Code	40411S
	Qty/Box	75
	Tidal Volume(ml)	150-300
	Dead Space(ml)	12
	Filtration Efficiency	BFE 99,999%; VFE 99,9%
	Humidification Efficiency	33 mg/l H ₂ O (250 ml. tid. vol.)
	Resistance to Flow	30 lt/min 13mm H ₂ O 60 lt/min 33mm H ₂ O 90 lt/min 55mm H ₂ O
	Weight (gr)	18,5
	Fittings	22F-15M/22M-15F

Bacterial-Viral HME Neonatal Filter with paper HME 	Code	40210
	Sterile Code	40210S
	Qty/Box	75
	Tidal Volume(ml)	50-150
	Dead Space(ml)	8
	Filtration Efficiency	BFE 99,999%; VFE 99,99%
	Humidification Efficiency	22 mg/l H ₂ O (250 ml. tid. vol.)
	Resistance to Flow	10 lt/min 13mm H ₂ O 15 lt/min 24mm H ₂ O 30 lt/min 60mm H ₂ O
	Weight (gr)	7,5
	Fittings	15M/15F

Bacterial-Viral HME Neonatal Filter Angled with paper HME 	Code	40211
	Sterile Code	40211S
	Qty/Box	75
	Tidal Volume(ml)	50-150
	Dead Space(ml)	8
	Filtration Efficiency	BFE 99,999%; VFE 99,99%
	Humidification Efficiency	22 mg/l H ₂ O (250 ml. tid. vol.)
	Resistance to Flow	10 lt/min 13mm H ₂ O 15 lt/min 24mm H ₂ O 30 lt/min 60mm H ₂ O
	Weight (gr)	13,5
	Fittings	15M/15F