SZUTEST

SERTİFİKA

Medikal Cihazlar Kalite Yönetim Sistemi

SERTİFİKA NO: 31816401

R Vent Medikal Üretim A.Ş.

29 Ekim Mah. Balkan Cad. No:33 TORBALI İZMİR/TÜRKİYE

EN ISO 13485:2016

Steril ve Steril Olmayan Tek Kullanımlık Solunum Sistemleri Üretimi ve Dağıtımı, EN ISO 11135 Gerekliliklerine göre Medikal Cihazların Sterilizasyon Servisi

Medikal Cihazlar Kalite Yönetim Sistemine yukarıda belirtilen kapsam dahilinde sahip olduğunu onaylar.

İlk Yayın Tarihi	13.06.2018
Yayın Tarihi	11.06.2021
Geçerlilik Tarihi	10.06.2024
Revizyon Tarih/No	11.06.2021 / 3

Digitally signed by Rusu Ghenadie
Date: 2021.12.21 07:47:44 EET
Reason: MoldSign Signature
Location: Moldova

TÜRKAK BDS NO
YS-B36C-C003

TÜRKAK
AB-0044-YS

Genel Müdür Yardımcısı

Bu belgenin doğrulanması belge üzerinde bulunan karekodların mobil cihazlara okutulması, http://public.szutest.com.tr adresinde gerekli bilgilerin girilmesi veya BDS no kullanılarak https://tbds.turkak.org.tr adresinden gerçekleştirilebilir.

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CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31816401

R Vent Medikal Üretim A.Ş.

29 Ekim Mah. Balkan Cad. No:33 TORBALI İZMİR/TÜRKİYE

EN ISO 13485:2016

Manufacturing and Distribution of Sterile and Non Sterile Disposable Breathing Systems, Sterilization Service for Medical Devices According to Requirements of EN ISO 11135

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	13.06.2018
Issue Date	11.06.2021
Expiry Date	10.06.2024
Revision Date/No	11.06.2021 / 3

TÜRKAK BDS NO
YS-B36C-C003

TÜRKAK
AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

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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), O_2 & Aerosol Therapy Set
(4) Steril Olmayan Maskeler, BVM (Resusitatör), O_2 & Aeresol Terapi Seti
(5) Sterile Closed Suction System
(5) Steril Kapalı Emiş Sistemi

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

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 kondisyondaki 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.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date/*Yayın Tarihi:* 2018-06-13
Revision No./ *Revizyon No.:* 02 Rev./*Rev.*
Revision Date/ *Revizyon Tarihi:* 2020-06-26

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

Manufacturer:

R-Vent Medikal Uretim A.S.
A: 29 Ekim Mah. Balkan Cad. No:33, Yazibasi beldesi, Torbali,
Izmir, Turkey

Document id. and Rev. Number:

DOC01-00

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

CE 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

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, ISO 5356-1:2015 , ISO 11135:2014, ISO 10993-1:2018, ISO 10993-5:2010, ISO 10993-10:2010, ISO 10993-12:2013, ISO 5362:2006 , ISO 5367:2014, ISO 13485:2016, ISO 9001:2015, TS EN ISO 15223-1:2016 , TS EN 1041+A1: 2014 , TS EN ISO 14644-1:2016 , TS EN ISO 11607-1: 2017 , TS EN ISO 11607-1: 2017 , TS EN ISO 14971:2013 , 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 : 2010 , TS EN 62366-1: 2015

Signature:

R VENT MEDİKAL ÜRETİM A.Ş.
29 Ekim Mah. Balkan Cad. No:33
Torbalı / İZMİR
Tel (232) 853 95 00 Fax (232) 853 94 95
Torbalı V.D. 734 081 2763
Mersis No 0734081276300001
Tic.Sic.No: 5444

Baha Bacak

QA/QC Manager

1.07.2020

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)

CODE KEY FOR BREATHING CIRCUITS:

Sample Code for Breathing Circuits,

12345678-0

Circuits																					
Tube type		Y-L Connector.		Limb		Water Trap		Circuit Lenght		Filter		Mask&Baloon		Accessory		Version					
1		2		3		4		5		6		7		8		-	0				
0	Universal F ped.	0	None	0	None	0	None	0	0,9 mt	0	None	0	None	0	None						
1	Adult-Corrugated	1	Y W/Out Port-L With Port	1	One Corrugated	1	One	1	1,0mt	1	B/V	1	Latex Baloon	1	single Heated Vire						
2	Adult-Smootbore	2	Y With Port-L W/Out Port	2	One Smootbore	2	Two	2	1,2mt	2	B/V HME	2	Neoprene Baloon	2	double Heated Vire						
3	Adult-Extendible	3	Y With Port- L With Port	3	One Extendible	3		3	1,5mt	3	Hepa Bacterial	3	Mask	3	Aerovent						
4	Pediyatrik-Corrugated	4	Y W/Out Port - L W/Out Port	4	2 Limb Corrugated	4		4	1,6mt	4	Hepa Bacterial, HME	4	Latex Baloon + Mask	4	GSL						
5	Pediyatrik-Smootbore	5	Y With Port – No L	5	2 Limb Smoothbore	5		5	1,8mt	5	B/V+B/V HME	5	Neoprene Baloon + Mask	5	proximal line						
6	Pediyatrik-Extendible	6	Y W/Out Port – No L	6	2 Limb Ext	6		6	2,0mt	6	B/V+B/V	6	CPAP Mask	6	IPPB With Port						
7	Neonatal-Corrugated	7	With Port swivel Y	7		7		7	2,4mt	7	B/V HME+ B/V HME	7	BPAP Mask	7	IPPB W/Out Port						
8	Neonatal-Smoothbore	8	W/Out Port swivel Y	8		8		8	3,0mt	8		8	CPAP Mask+peep valve	8	c.mount						
9	Universal F adult	9	Extra	9	Extra	9		9	Extra	9	Extra	9	Extra	9	Extra						

If sterile there will be an S Before "-"