SZUTEST

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

Digitally signed by Cojocaru Vera
Date: 2024.03.25 08:03:46 EET
Reason: MoldSign Signature
Location: Moldova

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31816401

R Vent Medikal Üretim A.Ş.

Yazıbaşı Mah. Balkan Cad. İztıpsan Apt. No:33/1 Torbalı, İzmir, 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	18.02.2022 / 4

TÜRKAK BDS NO
YS-7910-0E82

TÜRKAK
TS EN ISO/IEC 17021
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.

SZUTEST

CERTIFICATE INFO AMENDMENT

SERTİFİKA BİLGİ DEĞİŞİKLİĞİ

According to Article 120(3) of the Regulation (EU) 2017/745 on Medical Devices

(AB) 2017/745 Tıbbi Cihazlar Yönetmeliği Madde 120(3)'ye göre

Effected Certificate Number(s): *Etkilenen Sertifika Numarası(ları):*	**2195-MED-1816401**
Manufacturer: *Üretici*	**R Vent Medikal Üretim A.Ş.** Yazıbaşı Mah. Balkan Cad. İztıpsan Apt. No:33/1 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*
Model(s): *Model(ler)*	**No change** *Değişiklik mevcut değildir.*
Reference Report No: *Referans Rapor No*	MM0678-P008-R01
Definition of the Change: *Değişikliğin Tanımı*	**Address change** *Adres değişikliği*

SZUTEST, Notified Body 2195, declares and the above mentioned manufacturer has initiated an insignificant change according to Article 120(3) of (EU) 2017/745 and MDCG 2020-3 guidance and therefore the information on the effected 93/42/EEC certificate(s) has been changed as described above.

This document is a confirmation for authorities and cannot be used as other purposes.

2195 kimlik numaralı Onaylanmış Kuruluş SZUTEST, yukarıda belirtilen üreticinin (AB) 2017/745 Regülasyonu Madde 120(3)'e ve MDCG 2020-3 rehber dokümanına göre önemli olmayan bir değişiklik yürüttüğünü ve bu sebeple etkilenen 93/42/AT sertifika(lar)ındaki bilgilerin yukarıdaki gibi değiştiğini beyan eder.

Bu doküman yetkili otoriteler için bir onay niteliğinde olup farklı bir amaçla kullanılamaz.

Issue Date/*Yayın Tarihi:* 2022-02-18

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

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.
Yazıbaşı Mah. Balkan Cad. Iztipsan Apt. No:33
Tic.Sic.No:8444 Torbalı-İZMİR
Tel:(0232) 853 97 26 Fax:(0232) 853 97 30
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