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

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

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

Digitally signed by Cojocaru Vera
Date: 2023.04.11 07:21:54 EEST
Reason: MoldSign Signature
Location: Moldova

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

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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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:

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:

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

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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:

DOC03-00

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

NB No: 2195

Product Name	: ANESTHESIA MASKS (STANDARD & SCENTED), CPAP MASK,
Product Model Number(s)	: R-Vent, See below list for code
Description	: A malleable cone or cylinder placed over the nose and mouth or tra-cheal stoma, to deliver air, oxygen, or anaesthetic gases. This de-vice may be used with oxygen tubing, breathing circuits, various connectors or a manual resuscitator. Other attributes include: sterile , partial rebreathing, non-rebreathing, anesthesia (conductive), re-suscitation (includes one way valves), venturi applications, and it may have rebreathing (reservoir) bags attached. The device is also of a kind that is used over the nose and mouth as a protective barri-er.
GMDN Code(s)	: 46232

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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Mersis No:0734081276300012

Annex 1

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

Product Code	Product Name
8000	ANESTHESIA MASK, SIZE 0
8010	ANESTHESIA MASK, SIZE 1
8020	ANESTHESIA MASK, SIZE 2
8030	ANESTHESIA MASK, SIZE 3
8040	ANESTHESIA MASK, SIZE 4
8050	ANESTHESIA MASK, SIZE 5
8110	PVC FREE ANESTHESIA MASK # 1
8120	PVC FREE ANESTHESIA MASK # 2
8130	PVC FREE ANESTHESIA MASK # 3
8140	PVC FREE ANESTHESIA MASK # 4
8150	PVC FREE ANESTHESIA MASK # 5
8160	PVC FREE ANESTHESIA MASK # 6
8300	NASAL MASK # LARGE
8310	NASAL MASK # MEDIUM
8320	NASAL MASK # SMALL
8600	FULL FACE MASK # LARGE
8610	FULL FACE MASK # MEDIUM
8620	FULL FACE MASK # SMALL
8700	ANESTHESIA MASK, (SCENTED) SIZE 0
8710	ANESTHESIA MASK, (SCENTED) SIZE 1
8720	ANESTHESIA MASK, (SCENTED) SIZE 2
8730	ANESTHESIA MASK, (SCENTED) SIZE 3
8740	ANESTHESIA MASK, (SCENTED) SIZE 4
8750	ANESTHESIA MASK, (SCENTED) SIZE 5
8400	CPAP MASK, LARGE
8420	CPAP MASK, MEDIUM