SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31816401

R Vent Medikal Üretim A.Ş.

Yazıbaşı Mah. Balkan Cad. İztipsan Apt. No:33/1 Torbalı, İzmir, TÜRKİYE

EN ISO 13485:2016

Design, Development, Production, and Distribution of Sterile and Non-Sterile Single-Use Breathing Systems

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

First Issue Date	13.06.2018
Issue Date	10.06.2024
Expiry Date	09.06.2027
Revision Date/No	26.11.2025 / 6

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

TÜRKAK AB-0044-YS

TÜRKAK BDS NO YS-08CB-B1A2

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://tsbs.turkak.org.tr

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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 & Aerosol 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.

Issue Date/ *Yayın Tarihi:*	2018-06-13	Rukiye BALKAN
Revision No./ *Revizyon No.:*	02 Rev./*Rev.*	Deputy General Manager
Revision Date/ *Revizyon Tarihi:*	2020-06-26	*Genel Müdür Yardımcısı*

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

NOTIFIED BODY CONFIRMATION LETTER
No: MD0045-CL-01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 and implementing Regulation (EU) 2023/1194 amending implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain medical devices.

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name	R Vent Medikal Üretim A.Ş.
Address	Yazıbaşı Mah. Balkan Cad. İztıpsan Apt. No:33/1 Torbalı, İzmir, TÜRKİYE
SRN Number (if available)	TR-MF-000028282

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded, and for which the SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but SZUTEST Konformitätsbewertungsstelle GmbH has not yet taken responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance with the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR
- 31 December 2028 for Annex XVI products which do not require a clinical investigation.
- 31 December 2029 for Annex XVI products which require a clinical investigation.

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

MEHMET IŞIKLAR
General Manager

SZUTEST Konformitätsbewertungsstelle GmbH-NB 2975
Friedrich-Ebert-Anlage 36 D-60325 Frankfurt am Main /GERMANY

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

Table 1: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile and Non-Sterile Breathing Circuit Systems	Class IIa	Same	Certificate #1; 2195-MED-1816401 Revision No:2 Revision Date: 26.06.2020 Issue Date:13.06.2018 Expiry Date:26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Sterile and Non-Sterile Breathing Filters	Class IIa	Same	Certificate #1; 2195-MED-1816401 Revision No:2 Revision Date: 26.06.2020 Issue Date:13.06.2018 Expiry Date:26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Sterile and Non-Sterile Catheter Mounts	Class IIa	Same	Certificate #1; 2195-MED-1816401 Revision No:2 Revision Date: 26.06.2020 Issue Date:13.06.2018 Expiry Date:26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Non-sterile Masks, BVM (Resuscitator)	Class IIa	Same	Certificate #1; 2195-MED-1816401 Revision No:2 Revision Date: 26.06.2020 Issue Date:13.06.2018 Expiry Date:26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Sterile Closed Suction System	Class IIa	Same	Certificate #1; 2195-MED-1816401 Revision No:2 Revision Date: 26.06.2020 Issue Date:13.06.2018 Expiry Date:26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

Table 2: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	*N/A*	*N/A*	*N/A*

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/04/03	MD0045-CL-01	Initial issue
2024/09/25	MD0045-CL-01	O2 & Aerosol Therapy Set were removed from the list.
2024/09/27	MD0045-CL-01	The products have been transferred from Table 2 to Table 1.