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	: Bacterial/Viral HME Filter with Paper Sterile
Product Model Number(s)	: 40820S-4
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)	: 37597
Sterile	: Sterile
Classification / Rule ((acc. to MDD –	: 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 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, 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

Date of Signature: 29.11.2022

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

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.

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

Novo-Rvent Co-branding Article Number Structure

Rvent article number	31005000-6	61005000-1	99005000-7	99005208-2	99305020-10	99305024-4	00201020	00201020-1	316300S-2	316400S-1	21005000-5	40820S-4	40920S-2
NOVO article number	N20418010	N20418011	N20118010	N20118017	N20118030	N20118040	N22010002	N22010001	N22220310	N22222020	N20318030	N16110012	N16410010

Rvent article number	31307020-3	61307020-1	31007000-1	61007000-1	99007000-2	99307020-1	99307024-1	99308024-1	00101020-1	00101020	00101020-2	21007000-2	21227020-1	317300S-2	367300S-2	310000S-2
NOVO article number	N20424030	N20424031	N20424010	N20424011	N20124010	N20124030	N20124040	N20130040	N22010105	N22010102	N22010101	N20324010	N20324035	N22220410	N22220411	N22220412

25.11.2022
Datum

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Sign and company seal