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, 46816, 35530

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 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, 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:

TAYFUN ÖNÜR
General Manager

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	MINI BACTERIAL/VIRAL HME FILTER WITH LUER LOCK CAP
40211	MINI BACTERIAL/VIRAL HME FILTER WITH LUER LOCK CAP WITH ELBOW
40210S	MINI BACTERIAL/VIRAL HME FILTER WITH LUER LOCK CAP (STERILE EO)
40211S	MINI BACTERIAL/VIRAL HME FILTER I 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 WITH HME PAPER (STERILE 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)

Annex 2

LOT/PRODUCT BASED CUSTOMER REQUEST

Ürün Kodu *Product Code*	Ürün İsmi *Product name*	Ürün Lotu *Product Lot*	GMDN
40920	Bacterial/Viral Filter with Soft Cap	_	60837
40820	Bacterial/Viral HME Filter with Soft Cap	_	46816
40210	Mini Bacterial/Viral HME Filter with Luer Lock Cap	_	46816