

DOC01-05

**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 Declaration : Annex V, Article 3

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 their 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:

TAYFUN ÖNÜR
General Manager

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)

Annex 2**LOT/PRODUCT BASED CUSTOMER REQUEST**

Ürün Kodu <i>Product Code</i>	Ürün İsmi <i>Product name</i>	Ürün Lotu <i>Product Lot</i>	GMDN
11104010S	Anesthesia Circuit, Adult, Corrugated Tubing, Limb, Latex Bag, Sterile	–	37704