

Manufacturer:

R-Vent Medikal Üretim A.S.

Document id. and Rev. Number:29 Ekim Mah. Balkan Cad. No:33, Yazibasi Beldesi, Torbali,
Izmir, Turkey**DOC03-00****European Declaration of Conformity
to the Medical Device Directive, 93/42/EEC****C €2195**

Product Name	:	ANESTHESIA MASKS (STANDARD & SCENTED), NASAL MASK, CPAP MASK, FULL FACE MASK
Product Model Number(s)	:	R-VENT; see the attached table for codes.
Description	:	A malleable cone or cylinder placed over the nose and mouth or tracheal stoma, to deliver air, oxygen, or anaesthetic gases. This device may be used with oxygen tubing, breathing circuits, various connectors or a manual resuscitator. Other attributes include: sterile , partial rebreathing, non-rebreathing, anesthesia (conductive), resuscitation (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 barrier.
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 Üretim A.S. declares that the above product 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 its free distribution, sale and circulation in EEC.

2. As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate No : 2195-MED-1816401
QSys Certificate No : 31816401

Notified Body : **Szutest Uygunluk Değerlendirme (id. # 2195)**

All supporting documentation is retained at the manufacturer's premises

Signature on behalf of R-Vent Medikal Üretim A.S.

Date of :

Signature

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Tic.Sic.No: 5444

Baha BACAK
QA/QC Manager

Attachment to DOC03-00

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

Products:	Codes:
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
8700	ANESTHESIA MASK, SIZE 0
8710	ANESTHESIA MASK, SIZE 1
8720	ANESTHESIA MASK, SIZE 2
8730	ANESTHESIA MASK, SIZE 3
8740	ANESTHESIA MASK, SIZE 4
8750	ANESTHESIA MASK, SIZE 5
8400	CPAP MASK, LARGE
8420	CPAP MASK, MEDIUM
8600	FULL FACE MASK, LARGE
8610	FULL FACE MASK, MEDIUM
8620	FULL FACE MASK, SMALL
8300	NASAL MASK, LARGE
8310	NASAL MASK, MEDIUM
8320	NASAL MASK, SMALL