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:

DOC02-04

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

NB No: 2195

Product Name	: CLOSED SUCTION SYSTEM
Product Model Number(s)	: R-Vent, See below list for code
Description	The closed suction set applies in respiratory system disease, general anesthesia surgery and emergency salvage therapy. Closed Suction Set is also a device used for avoiding airborne or aerolized contamination and the possibility of clinician to contact with secretions. The closed suction set will connect the control valve and the tube of the aspirator when doctor use it.
GMDN code(s)	: 34923

The declaration covers the codes at Annex 1

Sterile	: Sterile
Classification / Rule ((acc. to MDD – Annex IX)	: Class II a / Rule 5
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, ISO 10993-1:2021, ISO 10993-5:2010, ISO 10993-11:2018, TS EN ISO 10993-12:2021, 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 14971:2020 , TS EN ISO 24971:2021, TS EN ISO 10993-14:2010 , TS EN 62366-1: 2015 , TS EN ISO 10651-4: 2010 , TS EN 13544-2+A1: 2010 , TS EN ISO 27427: 2019, ISO 8836:2021.

TAYFUN ÖNÜR
General Manager

Digitally signed by Rusu Ghenadie
Date: 2023.10.02 15:32:30 EEST
Reason: MoldSign Signature
Location: Moldova

Annex 1

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

Product Code	Product Name
24050	Closed Suction system 5FR
24060	Closed Suction System 6FR
24070	Closed Suction system 7FR
24080	Closed Suction System 8FR
24100	Closed Suction System 10FR
24120	Closed Suction System 12FR
24140	Closed Suction System 14FR
24160	Closed Suction System 16FR
72050	Closed Suction System, 72 Hours, 5FR
72060	Closed Suction System, 72 Hours, 6FR
72070	Closed Suction System, 72 Hours, 7FR
72080	Closed Suction System, 72 Hours, 8FR
72100	Closed Suction System, 72 Hours, 10FR
72100-1	Closed Suction System, 72 Hours, 10FR, with Catheter Mount
72120	Closed Suction System, 72 Hours, 12FR
72120-1	Closed Suction System, 72 Hours, 12FR, with Catheter Mount
72140	Closed Suction System, 72 Hours, 14FR
72140-1	Closed Suction System, 72 Hours, 14FR, with Catheter Mount
72160	Closed Suction System, 72 Hours, 16FR
72101	Closed Suction System, 72 Hours, 10FR, for Percutaneous Tracheostomy
72121	Closed Suction System, 72 Hours, 12FR, for Percutaneous Tracheostomy
72141	Closed Suction System, 72 Hours, 14FR, for Percutaneous Tracheostomy
72161	Closed Suction System, 72 Hours, 16FR, for Percutaneous Tracheostomy

Annex 2

LOT/PRODUCT BASED CUSTOMER REQUEST

Ürün Kodu *Product Code*	**Ürün İsmi** *Product name*	**Ürün Lotu** *Product Lot*	**GMDN**
72160	Closed Suction System, 72 Hours, 16FR	–	34923