

„CleanAir“ and ventilators.

Declaration according to article 22, 2017/745/EC

Technologie Institut Medizin GmbH (TIM), August - Thyssen - Str. 30, D-56070 Koblenz, is the legal manufacturer of the product “CleanAir” with models CA-01, CA-02 and CA-04.

The intended use of the product „CleanAir“ is collecting and evacuating expired patient gas at the expiration exit of ventilators. To connect the product “CleanAir” (CA) with the expiration exit of the below listed ventilators the manufacturer requires the use of ventilator specific adapters (VC). For the combination of listed ventilators with the product „CleanAir“ only the listed, ventilator specific adapters (VC), tested by the manufacturer of the product “CleanAir”, are allowed to be used.

List of ventilators compatible with “CleanAir”:

Manufacturer ventilator	Model Ventilator	Model Clean Air	Adapter Clean Air	Restrictions to be observed
Dräger Medical GmbH	Evita 2 Evita 2 dura Evita 2 cap	ORS-CA-01	ORS-VC-04	None
Dräger Medical GmbH	Evita 4 Evita XL	ORS-CA-01	ORS-VC-04	None
Dräger Medical GmbH	Evita 4 Evita XL	ORS-CA-04	ORS-VC-09	None
Dräger Medical GmbH	Evita Infinity V 300, Evita Infinity V 500	ORS-CA-01	ORS-VC-09	None
Dräger Medical GmbH	Evita Infinity V 600, Evita Infinity V 800	ORS-CA-01	ORS-VC-09	None
Dräger Medical GmbH	Savina 300	ORS-CA-01	ORS-VC-04	None
Dräger Medical GmbH	Savina 300	ORS-CA-04	ORS-VC-09	None
GE Healthcare Inc.	Engström- Carestation	ORS-CA-01	ORS-VC-02	None
GE Healthcare Inc.	Carescape R860	ORS-CA-01	ORS-VC-02	None
Hamilton Medical AG	G5, S1 with Exsp. valve (reusable)	ORS-CA-04	ORS-VC-10	With coaxial adult breathing system 190 cm: PEEP < 20 mbar due to risk of oscillation

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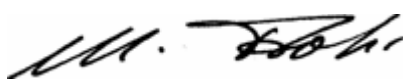
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List of ventilators compatible with “CleanAir” (cont.):

Manufacturer ventilator	Model Ventilator	Model Clean Air	Adapter Clean Air	Restrictions to be observed
Hamilton Medical AG	G5, S1 with Exsp. valve (reusable) and w/o humidifier H 900	ORS-CA-04	ORS-VC-10	With Dual Tube adult breathing system 160cm: PEEP < 10 mbar due to risk of oscillation
Hamilton Medical AG	C1	ORS-CA-01	ORS-VC-12	None
Hamilton Medical AG	C2 C3 C3S	ORS-CA-01	ORS-VC-11	None
Hamilton Medical AG	C6 C6S	ORS-CA-01	ORS-VC-11	None
Hamilton Medical AG	C6 C6S	ORS-CA-04	ORS-VC-16	None
Maquet Critical Care AB	Servo – i	ORS-CA-02	ORS-VC-08	PEEP < 20 mbar due to risk of oscillation
Maquet Critical Care AB	Servo – u	ORS-CA-02	ORS-VC-08	None
Maquet Critical Care AB	Servo – s	ORS-CA-01	ORS-VC-08	None
Medtronic (Nellcor, Puritan Bennett) Inc.	PB 840	ORS-CA-01	ORS-VC-06	None
Löwenstein Medical Innovation GmbH & Co. KG	Elisa 600 Elisa 800	ORS-CA-04	ORS-VC-17	None
Fritz Stephan GmbH	EVEin	ORS-CA-01	ORS-VC-18	PEEP < 15 mbar due to risk of oscillation

We, Technologie Institut Medizin GmbH (TIM), declare, that the listed combination of ventilator and “CleanAir” CA – model and „CleanAir“ – VC adapter was tested for mutual compatibility of the products for safety and their intended use according to the manufacturer's specifications and that these listed combinations can be used when any given restrictions and safety precautions in the instruction for use of the “CleanAir” and the ventilator are observed.

Koblenz, 14.06.2022



Markus Rohr

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