

„MIRUS™ System“ and ventilators.

Declaration according to article 12, 93/42/EEC

Technologie Institut Medizin GmbH (TIM), August - Thyssen - Str. 30, D-56070 Koblenz, is the legal manufacturer of the medical product „MIRUS Controller M“ with models **MC-MC-ISO**, **MC-MC-SEV** und **MC-MC-DES**.

The intended use of the „MIRUS System“ (see separate article 12 declaration), consisting of the medical products „MIRUS Controller M“, „MIRUS Reflector“ and „MIRUS Filter“, is to be inserted between patient’s tube and Y-piece of the breathing system and to deliver volatile anesthetic agents to a ventilated patient with a tidal volume larger than 200 ml.

List of ventilators compatible with "MIRUS System":

Manufacturer ventilator	Model ventilator	Gas type MIRUS System	Restrictions to be observed
Dräger Medical GmbH	Evita 2 Evita 2 dura Evita 2 cap	ISO, SEVO, DES	Do not use active humidification
Dräger Medical GmbH	Evita 4 Evita XL	ISO, SEVO, DES	Do not use active humidification
Dräger Medical GmbH	Evita Infinity V 300, Evita Infinity V 500	ISO, SEVO	Do not use active humidification
Dräger Medical GmbH	Evita Infinity V 300 Evita Infinity V 500	DES	Do not use active humidification. Negative leakage alarm (MVe > MVi) may occur at high MAC values.
Dräger Medical GmbH	Savina 300	ISO, SEVO, DES	Do not use active humidification
GE Healthcare Inc.	Engström- Carestation	ISO, SEVO, DES	Do not use active humidification
GE Healthcare Inc.	Carescape R860	ISO, SEVO, DES	Do not use active humidification
Hamilton Medical AG	G5 S1	ISO, SEVO, DES	Do not use active humidification
Hamilton Medical AG	C1 C2	ISO, SEVO, DES	Do not use active humidification
Hamilton Medical AG	C3 C3S	ISO, SEVO, DES	Do not use active humidification
Hamilton Medical AG	C6 C6S	ISO, SEVO, DES	Do not use active humidification

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List of ventilators compatible with "MIRUS System" (continued):

Manufacturer ventilator	Model ventilator	Gas type MIRUS System	Restrictions to be observed
Maquet Critical Care AB	Servo – i	ISO, SEVO, DES	Do not use active humidification
Maquet Critical Care AB	Servo – u	ISO, SEVO, DES	Do not use active humidification
Maquet Critical Care AB	Servo – s	ISO, SEVO, DES	Do not use active humidification
Medtronic (Nellcor, Puritan Bennett) Inc.	PB 840	ISO, SEVO, DES	Do not use active humidification
Löwenstein Medical Innovation GmbH & Co. KG	Elisa 600 Elisa 800	ISO, SEVO, DES	Do not use active humidification
Fritz Stephan GmbH	EVE in	ISO, SEVO, DES	Do not use active humidification

We, Technologie Institut Medizin GmbH (TIM), declare, that the listed combination of ventilator and “MIRUS System“ 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 “MIRUS System” and the ventilator are observed.

Koblenz, on 24.02.2021



Prof. Ing. Thomas P.Kriesmer



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