

„MIRUS™ System“.

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 „MIRUS System“ consists of the medical products „MIRUS Controller M“, „MIRUS Reflector“ and „MIRUS Filter“ and is to be inserted between patient's tube and the Y-piece of the breathing system. The intended use is the delivery of volatile anesthetic agents to a ventilated patient with a tidal volume larger than 200 ml.

List of „MIRUS Controller M“ and compatible medical products:

Manufacturer of medical product	Model of medical product	Gas type MIRUS System	Restrictions to be observed
PALL Medical, a division of PALL international Sàrl	MIRUS Filter MF1, MF1D	ISO, SEVO, DES	Only without active humidification
PALL Medical, a division of PALL international Sàrl	MIRUS Reflector MR1	ISO, SEVO, DES	Only without active humidification

We, Technologie Institut Medizin GmbH (TIM), declare, that the listed combination of

- “MIRUS Controller M”
- “MIRUS Reflector” and
- “MIRUS Filter”

called

- “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 Controller M”, “MIRUS Reflector” and “MIRUS Filter” are observed.

Koblenz, on 01.10.2019



Prof, Ing. Thomas P.Kriesmer
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