

EC Declaration of Conformity

in accordance with EC Directive 93/42/EEC concerning medical devices.

**Technologie Institut Medizin GmbH (TIM),
August - Thyssen Str. 30, 56070 Koblenz, Germany**

herewith declares under own responsibility as manufacturer that the Design, Construction and Version of the following Medical Device meet the Requirements of the European Directive 93/42/EEC.

Product identification:	SV-S-P SV-D-P
Medical Device Trade Name:	SmartVap™
Medical Device Class:	Class IIb according to MDD 93/42/EEC rule 11 Annex IX
Conformity Assessment Procedure:	According to Annex II of MDD 93/42/EEC Reg.-No. 44 232 117873 Issued by TÜV NORD CERT GmbH Langemarckstr. 20, 45141 Essen Notified body registered under # 0044
	This Declaration of Conformity is valid until 2024-01-20.
UDMNS Classification:	10-144 (vaporizer for volatile anaesthetic agents)

The Quality Management System has been approved in accordance with ISO 13485: 2016 by the Notified Body TÜV NORD CERT GmbH Langemarckstr. 20, 45141 Essen, Reg.No. 4422110117873.

Any modification to the Product not authorized by Technologie Institut Medizin GmbH (TIM) will invalidate this declaration.

Koblenz, 2020-09-16



Prof. Ing. Thomas P. Kriesmer
General Manager

