

EC Declaration of Conformity

The Company:

Andreas Fahl Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4a
51149 Köln, Germany
SRN: DE-MF-000006665

hereby account for the medical devices listed in the annex on which this declaration is based, that they conform to the following EC directive:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)

Product group	10000 - SILVERVENT®
Basic UDI-DI	405194810000SILVERVENTKU7
Class acc. to Directive 93/42/EEC	Class IIb
Classification Rule	5
REFs / Medical Devices	see annex on next page
Intended purpose	FAHL® tracheostomy tubes are intended to stabilise the tracheostomy following laryngectomy or tracheotomy. The tracheostomy tube is designed to keep the tracheostomy open. Tracheostomy tubes with cuff can be used for mechanical ventilation, including under anaesthesia. Percutec variants are designed for additional use in percutaneous dilatation tracheostomy.
Conformity assessment procedure	Medical devices listed in the annex conform to "essential requirements" of this directive as per Annex I. Conformity of the medical devices to Directive 93/42/EEC is declared as per Annex II. The manufacturer assumes sole responsibility for compliance with the requirements of Directive 93/42/EEC and all other Union legislation applicable to the medical devices listed in the annex below.

The manufacturer is subject to supervision by the notified body:
DNV MEDCERT GmbH (CE 0482), Pilatuspool 2, 20355 Hamburg, Germany

This Declaration of Conformity applies to all devices supplied after the production date until further notice. In the event of changes for the conformity assessment procedure, device alterations and changes to normative or regulatory requirements, conformity will be re-evaluated and declared again.

Cologne, 13.02.2025
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Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
10000-00	SILVERVENT® 1 IC, SIZE 0
10000-01	SILVERVENT® 1 IC, SIZE 1
10000-02	SILVERVENT® 1 IC, SIZE 2
10000-03	SILVERVENT® 1 IC, SIZE 3
10000-04	SILVERVENT® 1 IC, SIZE 4
10000-05	SILVERVENT® 1 IC, SIZE 5
10000-06	SILVERVENT® 1 IC, SIZE 6
10000-07	SILVERVENT® 1 IC, SIZE 7
10000-08	SILVERVENT® 1 IC, SIZE 8
10000-09	SILVERVENT® 1 IC, SIZE 9
10000-10	SILVERVENT® 1 IC, SIZE 10
10000-11	SILVERVENT® 1 IC, SIZE 11
10000-12	SILVERVENT® 1 IC, SIZE 12
10000-13	SILVERVENT® 1 IC, SIZE 13
10001-00	SILVERVENT® SIZE 0
10001-01	SILVERVENT® SIZE 1
10001-02	SILVERVENT® SIZE 2
10001-03	SILVERVENT® SIZE 3
10001-04	SILVERVENT® SIZE 4
10001-05	SILVERVENT® SIZE 5
10001-06	SILVERVENT® SIZE 6
10001-07	SILVERVENT® SIZE 7
10001-08	SILVERVENT® SIZE 8
10001-09	SILVERVENT® SIZE 9
10001-10	SILVERVENT® SIZE 10
10001-11	SILVERVENT® SIZE 11
10001-12	SILVERVENT® SIZE 12
10001-13	SILVERVENT® SIZE 13
10003-00	SILVERVENT® IC, Size 0
10003-01	SILVERVENT® IC, Size 1
10003-02	SILVERVENT® IC, Size 2

REF	Medical Device
10003-03	SILVERVENT® IC, Size 3
10003-04	SILVERVENT® IC, Size 4
10003-05	SILVERVENT® IC, Size 5
10003-06	SILVERVENT® IC, Size 6
10003-07	SILVERVENT® IC, Size 7
10003-08	SILVERVENT® IC, Size 8
10003-09	SILVERVENT® IC, Size 9
10003-10	SILVERVENT® IC, Size 10
10003-11	SILVERVENT® IC, Size 11
10003-12	SILVERVENT® IC, Size 12
10003-13	SILVERVENT® IC, Size 13
10004-00	SILVERVENT® ICU, Size 0
10004-01	SILVERVENT® ICU, Size 1
10004-02	SILVERVENT® ICU, Size 2
10004-03	SILVERVENT® ICU, Size 3
10004-04	SILVERVENT® ICU, Size 4
10004-05	SILVERVENT® ICU, Size 5
10004-06	SILVERVENT® ICU, Size 6
10004-07	SILVERVENT® ICU, Size 7
10004-08	SILVERVENT® ICU, Size 8
10004-09	SILVERVENT® ICU, Size 9
10004-10	SILVERVENT® ICU, Size 10
10004-11	SILVERVENT® ICU, Size 11
10004-12	SILVERVENT® ICU, Size 12
10004-13	SILVERVENT® ICU, Size 13
10500-00	SILVERVENT® UNI 1 ICU, SIZE 0
10500-01	SILVERVENT® UNI 1 ICU, SIZE 1
10500-02	SILVERVENT® UNI 1 ICU, SIZE 2
10500-03	SILVERVENT® UNI 1 ICU, SIZE 3
10500-04	SILVERVENT® UNI 1 ICU, SIZE 4
10500-05	SILVERVENT® UNI 1 ICU, SIZE 5
10500-06	SILVERVENT® UNI 1 ICU, SIZE 6

REF	Medical Device
10500-07	SILVERVENT® UNI 1 ICU, SIZE 7
10500-08	SILVERVENT® UNI 1 ICU, SIZE 8
10500-09	SILVERVENT® UNI 1 ICU, SIZE 9
10500-10	SILVERVENT® UNI 1 ICU, SIZE 10
10500-11	SILVERVENT® UNI 1 ICU, SIZE 11
10500-12	SILVERVENT® UNI 1 ICU, SIZE 12
10500-13	SILVERVENT® UNI 1 ICU, SIZE 13
10502-00	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 0
10502-01	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 1
10502-02	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 2
10502-03	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 3
10502-04	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 4
10502-05	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 5
10502-06	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 6
10502-07	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 7
10502-08	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 8
10502-09	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 9
10502-10	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 10
10502-11	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 11
10502-12	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 12
10502-13	SILVERVENT® UNI 1 IC + 1 ICU, SIZE 13
20000-00	SILVERVENT® LINGO-PHON 1 ICF, SIZE 0
20000-01	SILVERVENT® LINGO-PHON 1 ICF, SIZE 1
20000-02	SILVERVENT® LINGO-PHON 1 ICF, SIZE 2
20000-03	SILVERVENT® LINGO-PHON 1 ICF, SIZE 3
20000-04	SILVERVENT® LINGO-PHON 1 ICF, SIZE 4
20000-05	SILVERVENT® LINGO-PHON 1 ICF, SIZE 5
20000-06	SILVERVENT® LINGO-PHON 1 ICF, SIZE 6
20000-07	SILVERVENT® LINGO-PHON 1 ICF, SIZE 7
20000-08	SILVERVENT® LINGO-PHON 1 ICF, SIZE 8
20000-09	SILVERVENT® LINGO-PHON 1 ICF, SIZE 9
20000-10	SILVERVENT® LINGO-PHON 1 ICF, SIZE 10

REF	Medical Device
20000-11	SILVERVENT® LINGO-PHON 1 ICF, SIZE 11
20000-12	SILVERVENT® LINGO-PHON 1 ICF, SIZE 12
20000-13	SILVERVENT® LINGO-PHON 1 ICF, SIZE 13
20003-00	SILVERVENT® ICF, Size 0
20003-01	SILVERVENT® ICF,Size 1
20003-02	SILVERVENT® ICF,Size 2
20003-03	SILVERVENT® ICF, Size 3
20003-04	SILVERVENT® ICF, Size 4
20003-05	SILVERVENT® ICF, Size 5
20003-06	SILVERVENT® ICF, Size 6
20003-07	SILVERVENT® ICF, Size 7
20003-08	SILVERVENT® ICF, Size 8
20003-09	SILVERVENT® ICF, Size 9
20003-10	SILVERVENT® ICF, Size 10
20003-11	SILVERVENT® ICF, Size 11
20003-12	SILVERVENT® ICF, Size 12
20003-13	SILVERVENT® ICF, Size 13
20004-05	SILVERVENT® ICF-O2, Size 5
20004-06	SILVERVENT® ICF-O2, Size 6
20004-07	SILVERVENT® ICF-O2, Size 7
20004-08	SILVERVENT® ICF-O2, Size 8
20004-09	SILVERVENT® ICF-O2, Size 9
20004-10	SILVERVENT® ICF-O2, Size 10
20004-11	SILVERVENT® ICF-O2, Size 11
20004-12	SILVERVENT® ICF-O2, Size 12
20004-13	SILVERVENT® ICF-O2, Size 13
20300-05	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 5
20300-06	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 6
20300-07	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 7
20300-08	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 8
20300-09	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 9
20300-10	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 10

REF	Medical Device
20300-11	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 11
20300-12	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 12
20300-13	SILVERVENT® MULTI 1 ICU + 1 ICF-O2, SIZE 13