

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 legislation:

Regulation (EC) 2017/745 of 05 April 2017, Medical Device Regulation (MDR)

Product group	Spiraflex®
Basic UDI-DI	4051948X17503SPIRAFLXVAFX
Class acc. to EC regulation 2017/745 Annex VIII	Class IIb
Classification Rule	8
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. Percutan variants are designed for additional use in percutaneous dilatation tracheostomy.
Conformity assessment procedure	Medical devices listed in the annex conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I. The conformity of medical devices is declared according to EC regulation 2017/745, Annex IX. Certificate No.: 1320GB448251015 The manufacturer assumes sole responsibility for compliance with the requirements of EC regulation 2017/745 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, 15.10.2025

Andreas Fahl
Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4a
D-51149 Köln (Pötz-Grembenthalhofen)

Christoph Bernads
Person Responsible for Regulatory Compliance

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
X17503-06	Spiraflex® Uni Cuff, SIZE 6
X17503-06-P	Spiraflex® Percutan Uni Cuff, SIZE 6
X17503-07	Spiraflex® Uni Cuff, SIZE 7
X17503-07-P	Spiraflex® Percutan Uni Cuff, SIZE 7
X17503-08	Spiraflex® Uni Cuff, SIZE 8
X17503-08-P	Spiraflex® Percutan Uni Cuff, SIZE 8
X17503-09	Spiraflex® Uni Cuff, SIZE 9
X17503-09-P	Spiraflex® Percutan Uni Cuff, SIZE 9
X17503-10	Spiraflex® Uni Cuff, SIZE 10
X17503-10-P	Spiraflex® Percutan Uni Cuff, SIZE 10
X17503-11	Spiraflex® Uni Cuff, SIZE 11
X17503-11-P	Spiraflex® Percutan Uni Cuff, SIZE 11
X17504-06	Spiraflex® Uni, SIZE 6
X17504-07	Spiraflex® Uni, SIZE 7
X17504-08	Spiraflex® Uni, SIZE 8
X17504-09	Spiraflex® Uni, SIZE 9
X17504-10	Spiraflex® Uni, SIZE 10
X17504-11	Spiraflex® Uni, SIZE 11
X17506-06	Spiraflex® Short Uni 2 ICX, SIZE 6
X17506-07	Spiraflex® Short Uni 2 ICX, SIZE 7
X17506-08	Spiraflex® Short Uni 2 ICX, SIZE 8
X17506-09	Spiraflex® Short Uni 2 ICX, SIZE 9
X17506-10	Spiraflex® Short Uni 2 ICX, SIZE 10
X17506-11	Spiraflex® Short Uni 2 ICX, SIZE 11
X17507-06	Spiraflex® Short Uni Cuff 2 ICX, SIZE 6
X17507-07	Spiraflex® Short Uni Cuff 2 ICX, SIZE 7
X17507-08	Spiraflex® Short Uni Cuff 2 ICX, SIZE 8
X17507-09	Spiraflex® Short Uni Cuff 2 ICX, SIZE 9
X17507-10	Spiraflex® Short Uni Cuff 2 ICX, SIZE 10
X17507-11	Spiraflex® Short Uni Cuff 2 ICX, SIZE 11
X17508-06	Spiraflex® Short Uni Lingo-Phon 1 ICX + 1 ICFX + SV, SIZE 6

REF	Medical Device
X17508-07	Spiraflex® Short Uni Lingo-Phon 1 ICX + 1 ICFX + SV, SIZE 7
X17508-08	Spiraflex® Short Uni Lingo-Phon 1 ICX + 1 ICFX + SV, SIZE 8
X17508-09	Spiraflex® Short Uni Lingo-Phon 1 ICX + 1 ICFX + SV, SIZE 9
X17508-10	Spiraflex® Short Uni Lingo-Phon 1 ICX + 1 ICFX + SV, SIZE 10
X17508-11	Spiraflex® Short Uni Lingo-Phon 1 ICX + 1 ICFX + SV, SIZE 11
X17509-06	Spiraflex® Short Uni Lingo-Phon Cuff 1 ICX + 1 ICFX + SV, SIZE 6
X17509-07	Spiraflex® Short Uni Lingo-Phon Cuff 1 ICX + 1 ICFX + SV, SIZE 7
X17509-08	Spiraflex® Short Uni Lingo-Phon Cuff 1 ICX + 1 ICFX + SV, SIZE 8
X17509-09	Spiraflex® Short Uni Lingo-Phon Cuff 1 ICX + 1 ICFX + SV, SIZE 9
X17509-10	Spiraflex® Short Uni Lingo-Phon Cuff 1 ICX + 1 ICFX + SV, SIZE 10
X17509-11	Spiraflex® Short Uni Lingo-Phon Cuff 1 ICX + 1 ICFX + SV, SIZE 11
X17516-06	Spiraflex® Short ICX, SIZE 6
X17516-07	Spiraflex® Short ICX, SIZE 7
X17516-08	Spiraflex® Short ICX, SIZE 8
X17516-09	Spiraflex® Short ICX, SIZE 9
X17516-10	Spiraflex® Short ICX, SIZE 10
X17516-11	Spiraflex® Short ICX, SIZE 11
X17517-06	Spiraflex® Short ICFX, SIZE 6
X17517-07	Spiraflex® Short ICFX, SIZE 7
X17517-08	Spiraflex® Short ICFX, SIZE 8
X17517-09	Spiraflex® Short ICFX, SIZE 9
X17517-10	Spiraflex® Short ICFX, SIZE 10
X17517-11	Spiraflex® Short ICFX, SIZE 11
X17519-07	Spiraflex® Uni Cuff XL, SIZE 7
X17519-07-P	Spiraflex® Percutan Uni Cuff XL, SIZE 7
X17519-08	Spiraflex® Uni Cuff XL, SIZE 8
X17519-08-P	Spiraflex® Percutan Uni Cuff XL, SIZE 8
X17519-09	Spiraflex® Uni Cuff XL, SIZE 9
X17519-09-P	Spiraflex® Percutan Uni Cuff XL, SIZE 9
X17519-10	Spiraflex® Uni Cuff XL, SIZE 10
X17519-10-P	Spiraflex® Percutan Uni Cuff XL, SIZE 10
X17519-11	Spiraflex® Uni Cuff XL, SIZE 11

REF	Medical Device
X17519-11-P	Spiraflex® Percutan Uni Cuff XL, SIZE 11
X17520-06	Spiraflex® MRT Uni Cuff, SIZE 6
X17520-07	Spiraflex® MRT Uni Cuff, SIZE 7
X17520-08	Spiraflex® MRT Uni Cuff, SIZE 8
X17520-09	Spiraflex® MRT Uni Cuff, SIZE 9
X17520-10	Spiraflex® MRT Uni Cuff, SIZE 10
X17520-11	Spiraflex® MRT Uni Cuff, SIZE 11
X17523-07	Spiraflex® Uni Cuff-Suction, SIZE 7
X17523-07-P	Spiraflex® Percutan Uni Cuff-Suction, SIZE 7
X17523-08	Spiraflex® Uni Cuff-Suction, SIZE 8
X17523-08-P	Spiraflex® Percutan Uni Cuff-Suction, SIZE 8
X17523-09	Spiraflex® Uni Cuff-Suction, SIZE 9
X17523-09-P	Spiraflex® Percutan Uni Cuff-Suction, SIZE 9
X17523-10	Spiraflex® Uni Cuff-Suction, SIZE 10
X17523-10-P	Spiraflex® Percutan Uni Cuff-Suction, SIZE 10
X17523-11	Spiraflex® Uni Cuff-Suction, SIZE 11
X17523-11-P	Spiraflex® Percutan Uni Cuff-Suction, SIZE 11
X17524-07	Spiraflex® Uni Cuff-Suction XL, SIZE 7
X17524-07-P	Spiraflex® Percutan Uni Cuff-Suction XL, SIZE 7
X17524-08	Spiraflex® Uni Cuff-Suction XL, SIZE 8
X17524-08-P	Spiraflex® Percutan Uni Cuff-Suction XL, SIZE 8
X17524-09	Spiraflex® Uni Cuff-Suction XL, SIZE 9
X17524-09-P	Spiraflex® Percutan Uni Cuff-Suction XL, SIZE 9
X17524-10	Spiraflex® Uni Cuff-Suction XL, SIZE 10
X17524-10-P	Spiraflex® Percutan Uni Cuff-Suction XL, SIZE 10
X17543-06	Spiraflex® ICX, SIZE 6
X17543-07	Spiraflex® ICX, SIZE 7
X17543-08	Spiraflex® ICX, SIZE 8
X17543-09	Spiraflex® ICX, SIZE 9
X17543-10	Spiraflex® ICX, SIZE 10
X17543-11	Spiraflex® ICX, SIZE 11
X17549-07	Spiraflex® ICX XL, SIZE 7

REF	Medical Device
X17549-08	Spiraflex® ICX XL, SIZE 8
X17549-09	Spiraflex® ICX XL, SIZE 9
X17549-10	Spiraflex® ICX XL, SIZE 10
X17549-11	Spiraflex® ICX XL, SIZE 11