

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	Duratwix®
Basic UDI-DI	4051948X19201DURATWIXTKCH
Class acc. to EC regulation 2017/745 Annex VIII	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 "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
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August-Horch-Straße 4a
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Christoph Bernads
Person Responsible for Regulatory Compliance

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
X19201-07	Duratwix® Uni, SIZE 7
X19201-08	Duratwix® Uni, SIZE 8
X19201-09	Duratwix® Uni, SIZE 9
X19201-10	Duratwix® Uni, SIZE 10
X19202-07	Duratwix® Uni short, SIZE 7
X19202-08	Duratwix® Uni short, SIZE 8
X19202-09	Duratwix® Uni short, SIZE 9
X19202-10	Duratwix® Uni short, SIZE 10
X19211-06	Duratwix® Uni-Vario 1 ICU + 1 ICV, SIZE 6
X19211-07	Duratwix® Uni-Vario 1 ICU + 1 ICV, SIZE 7
X19211-08	Duratwix® Uni-Vario 1 ICU + 1 ICV, SIZE 8
X19211-09	Duratwix® Uni-Vario 1 ICU + 1 ICV, SIZE 9
X19211-10	Duratwix® Uni-Vario 1 ICU + 1 ICV, SIZE 10
X19212-07	Duratwix® Uni-Vario short 1 ICU + 1 ICV, SIZE 7
X19212-08	Duratwix® Uni-Vario short 1 ICU + 1 ICV, SIZE 8
X19212-09	Duratwix® Uni-Vario short 1 ICU + 1 ICV, SIZE 9
X19212-10	Duratwix® Uni-Vario short 1 ICU + 1 ICV, SIZE 10
X19213-06	Duratwix® Uni 2 ICU, SIZE 6
X19213-07	Duratwix® Uni 2 ICU, SIZE 7
X19213-08	Duratwix® Uni 2 ICU, SIZE 8
X19213-09	Duratwix® Uni 2 ICU, SIZE 9
X19213-10	Duratwix® Uni 2 ICU, SIZE 10
X19214-07	Duratwix® Uni short 2 ICU, SIZE 7
X19214-08	Duratwix® Uni short 2 ICU, SIZE 8
X19214-09	Duratwix® Uni short 2 ICU, SIZE 9
X19214-10	Duratwix® Uni short 2 ICU, SIZE 10
X19261-06	Duratwix® Uni-Vario Lingo 1 ICV + 1 ICFU, SIZE 6
X19261-07	Duratwix® Uni-Vario Lingo 1 ICV + 1 ICFU, SIZE 7
X19261-08	Duratwix® Uni-Vario Lingo 1 ICV + 1 ICFU, SIZE 8
X19261-09	Duratwix® Uni-Vario Lingo 1 ICV + 1 ICFU, SIZE 9
X19261-10	Duratwix® Uni-Vario Lingo 1 ICV + 1 ICFU, SIZE 10

REF	Medical Device
X19262-07	Duratwix® Uni-Vario Lingo short 1 ICV + 1 ICFU, SIZE 7
X19262-08	Duratwix® Uni-Vario Lingo short 1 ICV + 1 ICFU, SIZE 8
X19262-09	Duratwix® Uni-Vario Lingo short 1 ICV + 1 ICFU, SIZE 9
X19262-10	Duratwix® Uni-Vario Lingo short 1 ICV + 1 ICFU, SIZE 10
X19263-06	Duratwix® Uni Lingo 1 ICU + 1 ICFU, SIZE 6
X19263-07	Duratwix® Uni Lingo 1 ICU + 1 ICFU, SIZE 7
X19263-08	Duratwix® Uni Lingo 1 ICU + 1 ICFU, SIZE 8
X19263-09	Duratwix® Uni Lingo 1 ICU + 1 ICFU, SIZE 9
X19263-10	Duratwix® Uni Lingo 1 ICU + 1 ICFU, SIZE 10
X19264-07	Duratwix® Uni Lingo short 1 ICU + 1 ICFU, SIZE 7
X19264-08	Duratwix® Uni Lingo short 1 ICU + 1 ICFU, SIZE 8
X19264-09	Duratwix® Uni Lingo short 1 ICU + 1 ICFU, SIZE 9
X19264-10	Duratwix® Uni Lingo short 1 ICU + 1 ICFU, SIZE 10
X19271-07	Duratwix® Uni Lingo, SIZE 7
X19271-08	Duratwix® Uni Lingo, SIZE 8
X19271-09	Duratwix® Uni Lingo, SIZE 9
X19271-10	Duratwix® Uni Lingo, SIZE 10
X19272-07	Duratwix® Uni Lingo short, SIZE 7
X19272-08	Duratwix® Uni Lingo short, SIZE 8
X19272-09	Duratwix® Uni Lingo short, SIZE 9
X19272-10	Duratwix® Uni Lingo short, SIZE 10
X19601-07	Duratwix® Uni Cuff, SIZE 7
X19601-08	Duratwix® Uni Cuff, SIZE 8
X19601-09	Duratwix® Uni Cuff, SIZE 9
X19601-10	Duratwix® Uni Cuff, SIZE 10
X19602-07	Duratwix® Uni Cuff short, SIZE 7
X19602-08	Duratwix® Uni Cuff short, SIZE 8
X19602-09	Duratwix® Uni Cuff short, SIZE 9
X19602-10	Duratwix® Uni Cuff short, SIZE 10
X19611-06	Duratwix® Uni-Vario Cuff 1 ICU + 1 ICV, SIZE 6
X19611-07	Duratwix® Uni-Vario Cuff 1 ICU + 1 ICV, SIZE 7
X19611-08	Duratwix® Uni-Vario Cuff 1 ICU + 1 ICV, SIZE 8

REF	Medical Device
X19611-09	Duratwix® Uni-Vario Cuff 1 ICU + 1 ICV, SIZE 9
X19611-10	Duratwix® Uni-Vario Cuff 1 ICU + 1 ICV, SIZE 10
X19612-07	Duratwix® Uni-Vario Cuff short 1 ICU + 1 ICV, SIZE 7
X19612-08	Duratwix® Uni-Vario Cuff short 1 ICU + 1 ICV, SIZE 8
X19612-09	Duratwix® Uni-Vario Cuff short 1 ICU + 1 ICV, SIZE 9
X19612-10	Duratwix® Uni-Vario Cuff short 1 ICU + 1 ICV, SIZE 10
X19613-06	Duratwix® Uni Cuff 2 ICU, SIZE 6
X19613-07	Duratwix® Uni Cuff 2 ICU, SIZE 7
X19613-08	Duratwix® Uni Cuff 2 ICU, SIZE 8
X19613-09	Duratwix® Uni Cuff 2 ICU, SIZE 9
X19613-10	Duratwix® Uni Cuff 2 ICU, SIZE 10
X19614-07	Duratwix® Uni Cuff short 2 ICU, SIZE 7
X19614-08	Duratwix® Uni Cuff short 2 ICU, SIZE 8
X19614-09	Duratwix® Uni Cuff short 2 ICU, SIZE 9
X19614-10	Duratwix® Uni Cuff short 2 ICU, SIZE 10
X19661-06	Duratwix® Uni-Vario Lingo-Cuff 1 ICV + 1 ICFU, SIZE 6
X19661-07	Duratwix® Uni-Vario Lingo-Cuff 1 ICV + 1 ICFU, SIZE 7
X19661-08	Duratwix® Uni-Vario Lingo-Cuff 1 ICV + 1 ICFU, SIZE 8
X19661-09	Duratwix® Uni-Vario Lingo-Cuff 1 ICV + 1 ICFU, SIZE 9
X19661-10	Duratwix® Uni-Vario Lingo-Cuff 1 ICV + 1 ICFU, SIZE 10
X19662-07	Duratwix® Uni-Vario Lingo-Cuff short 1 ICV + 1 ICFU, SIZE 7
X19662-08	Duratwix® Uni-Vario Lingo-Cuff short 1 ICV + 1 ICFU, SIZE 8
X19662-09	Duratwix® Uni-Vario Lingo-Cuff short 1 ICV + 1 ICFU, SIZE 9
X19662-10	Duratwix® Uni-Vario Lingo-Cuff short 1 ICV + 1 ICFU, SIZE 10
X19663-06	Duratwix® Uni Lingo-Cuff 1 ICU + 1 ICFU, SIZE 6
X19663-07	Duratwix® Uni Lingo-Cuff 1 ICU + 1 ICFU, SIZE 7
X19663-08	Duratwix® Uni Lingo-Cuff 1 ICU + 1 ICFU, SIZE 8
X19663-09	Duratwix® Uni Lingo-Cuff 1 ICU + 1 ICFU, SIZE 9
X19663-10	Duratwix® Uni Lingo-Cuff 1 ICU + 1 ICFU, SIZE 10
X19664-07	Duratwix® Uni Lingo-Cuff short 1 ICU + 1 ICFU, SIZE 7
X19664-08	Duratwix® Uni Lingo-Cuff short 1 ICU + 1 ICFU, SIZE 8
X19664-09	Duratwix® Uni Lingo-Cuff short 1 ICU + 1 ICFU, SIZE 9

REF	Medical Device
X19664-10	Duratwix® Uni Lingo-Cuff short 1 ICU + 1 ICFU, SIZE 10
X19801-06	Duratwix® IC, SIZE 6
X19801-07	Duratwix® IC, SIZE 7
X19801-08	Duratwix® IC, SIZE 8
X19801-09	Duratwix® IC, SIZE 9
X19801-10	Duratwix® IC, SIZE 10
X19802-07	Duratwix® IC short, SIZE 7
X19802-08	Duratwix® IC short, SIZE 8
X19802-09	Duratwix® IC short, SIZE 9
X19802-10	Duratwix® IC short, SIZE 10
X19811-06	Duratwix® ICU, SIZE 6
X19811-07	Duratwix® ICU, SIZE 7
X19811-08	Duratwix® ICU, SIZE 8
X19811-09	Duratwix® ICU, SIZE 9
X19811-10	Duratwix® ICU, SIZE 10
X19812-07	Duratwix® ICU short, SIZE 7
X19812-08	Duratwix® ICU short, SIZE 8
X19812-09	Duratwix® ICU short, SIZE 9
X19812-10	Duratwix® ICU short, SIZE 10
X19821-06	Duratwix® ICV, SIZE 6
X19821-07	Duratwix® ICV, SIZE 7
X19821-08	Duratwix® ICV, SIZE 8
X19821-09	Duratwix® ICV, SIZE 9
X19821-10	Duratwix® ICV, SIZE 10
X19822-07	Duratwix® ICV short, SIZE 7
X19822-08	Duratwix® ICV short, SIZE 8
X19822-09	Duratwix® ICV short, SIZE 9
X19822-10	Duratwix® ICV short, SIZE 10
X19831-06	Duratwix® ICK, SIZE 6
X19831-07	Duratwix® ICK, SIZE 7
X19831-08	Duratwix® ICK, SIZE 8
X19831-09	Duratwix® ICK, SIZE 9

REF	Medical Device
X19831-10	Duratwix® ICK, SIZE 10
X19832-07	Duratwix® ICK short, SIZE 7
X19832-08	Duratwix® ICK short, SIZE 8
X19832-09	Duratwix® ICK short, SIZE 9
X19832-10	Duratwix® ICK short, SIZE 10
X19841-06	Duratwix® Phon ICF, SIZE 6
X19841-07	Duratwix® Phon ICF, SIZE 7
X19841-08	Duratwix® Phon ICF, SIZE 8
X19841-09	Duratwix® Phon ICF, SIZE 9
X19841-10	Duratwix® Phon ICF, SIZE 10
X19842-07	Duratwix® Phon ICF short, SIZE 7
X19842-08	Duratwix® Phon ICF short, SIZE 8
X19842-09	Duratwix® Phon ICF short, SIZE 9
X19842-10	Duratwix® Phon ICF short, SIZE 10
X19861-06	Duratwix® ICFU, SIZE 6
X19861-07	Duratwix® ICFU, SIZE 7
X19861-08	Duratwix® ICFU, SIZE 8
X19861-09	Duratwix® ICFU, SIZE 9
X19861-10	Duratwix® ICFU, SIZE 10
X19862-07	Duratwix® ICFU short, SIZE 7
X19862-08	Duratwix® ICFU short, SIZE 8
X19862-09	Duratwix® ICFU short, SIZE 9
X19862-10	Duratwix® ICFU short, SIZE 10
X19871-06	Duratwix® ICFV, SIZE 6
X19871-07	Duratwix® ICFV, SIZE 7
X19871-08	Duratwix® ICFV, SIZE 8
X19871-09	Duratwix® ICFV, SIZE 9
X19871-10	Duratwix® ICFV, SIZE 10
X19872-07	Duratwix® ICFV short, SIZE 7
X19872-08	Duratwix® ICFV short, SIZE 8
X19872-09	Duratwix® ICFV short, SIZE 9
X19872-10	Duratwix® ICFV short, SIZE 10

REF	Medical Device
X19881-06	Duratwix® ICFK, SIZE 6
X19881-07	Duratwix® ICFK, SIZE 7
X19881-08	Duratwix® ICFK, SIZE 8
X19881-09	Duratwix® ICFK, SIZE 9
X19881-10	Duratwix® ICFK, SIZE 10
X19882-07	Duratwix® ICFK short, SIZE 7
X19882-08	Duratwix® ICFK short, SIZE 8
X19882-09	Duratwix® ICFK short, SIZE 9
X19882-10	Duratwix® ICFK short, SIZE 10