

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	Laryngotec®, Phontrach®
Basic UDI-DI	4051948X114720LRYNGTCTKRJ
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

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Person Responsible for Regulatory Compliance

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
X114720-0744	Laryngotec® Kombi Lingo, SIZE 7/44
X114720-0762	Laryngotec® Kombi Lingo, SIZE 7/62
X114720-0844	Laryngotec® Kombi Lingo, SIZE 8/44
X114720-0862	Laryngotec® Kombi Lingo, SIZE 8/62
X114720-0870	Laryngotec® Kombi Lingo, SIZE 8/70
X114720-0944	Laryngotec® Kombi Lingo, SIZE 9/44
X114720-0962	Laryngotec® Kombi Lingo, SIZE 9/62
X114720-0975	Laryngotec® Kombi Lingo, SIZE 9/75
X114720-1044	Laryngotec® Kombi Lingo, SIZE 10/44
X114720-1062	Laryngotec® Kombi Lingo, SIZE 10/62
X114720-1085	Laryngotec® Kombi Lingo, SIZE 10/85
X114720-1144	Laryngotec® Kombi Lingo, SIZE 11/44
X114720-1162	Laryngotec® Kombi Lingo, SIZE 11/62
X114720-1187	Laryngotec® Kombi Lingo, SIZE 11/87
X114720-1244	Laryngotec® Kombi Lingo, SIZE 12/44
X114720-1262	Laryngotec® Kombi Lingo, SIZE 12/62
X114720-1290	Laryngotec® Kombi Lingo, SIZE 12/90
X114820-0744	Laryngotec® Kombi Clip Lingo, SIZE 7/44
X114820-0762	Laryngotec® Kombi Clip Lingo, SIZE 7/62
X114820-0844	Laryngotec® Kombi Clip Lingo, SIZE 8/44
X114820-0862	Laryngotec® Kombi Clip Lingo, SIZE 8/62
X114820-0944	Laryngotec® Kombi Clip Lingo, SIZE 9/44
X114820-0962	Laryngotec® Kombi Clip Lingo, SIZE 9/62
X114820-1044	Laryngotec® Kombi Clip Lingo, SIZE 10/44
X114820-1062	Laryngotec® Kombi Clip Lingo, SIZE 10/62
X114820-1085	Laryngotec® Kombi Clip Lingo, SIZE 10/85
X114820-1144	Laryngotec® Kombi Clip Lingo, SIZE 11/44
X114820-1162	Laryngotec® Kombi Clip Lingo, SIZE 11/62
X114820-1244	Laryngotec® Kombi Clip Lingo, SIZE 12/44
X114820-1262	Laryngotec® Kombi Clip Lingo, SIZE 12/62
X114820-1344	Laryngotec® Kombi Clip Lingo, SIZE 13/44

REF	Medical Device
X114820-1362	Laryngotec® Kombi Clip Lingo, SIZE 13/62
X114830-0744	Laryngotec® Kombi Clip, SIZE 7/44
X114830-0844	Laryngotec® Kombi Clip, SIZE 8/44
X114830-0862	Laryngotec® Kombi Clip, SIZE 8/62
X114830-0944	Laryngotec® Kombi Clip, SIZE 9/44
X114830-0962	Laryngotec® Kombi Clip, SIZE 9/62
X114830-0975	Laryngotec® Kombi Clip, SIZE 9/75
X114830-1044	Laryngotec® Kombi Clip, SIZE 10/44
X114830-1062	Laryngotec® Kombi Clip, SIZE 10/62
X114830-1085	Laryngotec® Kombi Clip, SIZE 10/85
X114830-1144	Laryngotec® Kombi Clip, SIZE 11/44
X114830-1162	Laryngotec® Kombi Clip, SIZE 11/62
X114830-1187	Laryngotec® Kombi Clip, SIZE 11/87
X114830-1244	Laryngotec® Kombi Clip, SIZE 12/44
X114830-1262	Laryngotec® Kombi Clip, SIZE 12/62
X114830-1344	Laryngotec® Kombi Clip, SIZE 13/44
X114830-1362	Laryngotec® Kombi Clip, SIZE 13/62
X114920-0744	Laryngotec® Kombi, SIZE 7/44
X114920-0762	Laryngotec® Kombi, SIZE 7/62
X114920-0844	Laryngotec® Kombi, SIZE 8/44
X114920-0862	Laryngotec® Kombi, SIZE 8/62
X114920-0870	Laryngotec® Kombi, SIZE 8/70
X114920-0944	Laryngotec® Kombi, SIZE 9/44
X114920-0962	Laryngotec® Kombi, SIZE 9/62
X114920-0975	Laryngotec® Kombi, SIZE 9/75
X114920-1044	Laryngotec® Kombi, SIZE 10/44
X114920-1062	Laryngotec® Kombi, SIZE 10/62
X114920-1085	Laryngotec® Kombi, SIZE 10/85
X114920-1144	Laryngotec® Kombi, SIZE 11/44
X114920-1162	Laryngotec® Kombi, SIZE 11/62
X114920-1187	Laryngotec® Kombi, SIZE 11/87
X114920-1244	Laryngotec® Kombi, SIZE 12/44

REF	Medical Device
X114920-1262	Laryngotec® Kombi, SIZE 12/62
X114920-1290	Laryngotec® Kombi, SIZE 12/90
X114920-1344	Laryngotec® Kombi, SIZE 13/44
X114920-1362	Laryngotec® Kombi, SIZE 13/62
X114920-1390	Laryngotec® Kombi, SIZE 13/90
X114930-07	Phontrach® Kombi Lingo Phon, SIZE 7
X114930-08	Phontrach® Kombi Lingo Phon, SIZE 8
X114930-09	Phontrach® Kombi Lingo Phon, SIZE 9
X114930-10	Phontrach® Kombi Lingo Phon, SIZE 10
X114930-11	Phontrach® Kombi Lingo Phon, SIZE 11
X114930-12	Phontrach® Kombi Lingo Phon, SIZE 12
X114930-13	Phontrach® Kombi Lingo Phon, SIZE 13
X115950-08	Laryngotec® Kombi Stoma Button Fix, SIZE 8
X115950-09	Laryngotec® Kombi Stoma Button Fix, SIZE 9
X115950-10	Laryngotec® Kombi Stoma Button Fix, SIZE 10
X115950-11	Laryngotec® Kombi Stoma Button Fix, SIZE 11
X115950-12	Laryngotec® Kombi Stoma Button Fix, SIZE 12
X115960-08	Laryngotec® Kombi Stoma Button Fix short, SIZE 8
X115960-09	Laryngotec® Kombi Stoma Button Fix short, SIZE 9
X115960-10	Laryngotec® Kombi Stoma Button Fix short, SIZE 10
X115960-11	Laryngotec® Kombi Stoma Button Fix short, SIZE 11
X115960-12	Laryngotec® Kombi Stoma Button Fix short, SIZE 12