

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	LARYVOX® Tape
Basic UDI-DI	405194848050LAVXTAPE+TA6T
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	1
REFs / Medical Devices	see annex on next page
Intended purpose	Base plates are an attachment system for daily use of HME filter cassettes or tracheostoma valves with a 22 mm adapter.
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 based on technical documentation according to EC regulation 2017/745, Annex II and III. 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.

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, 15.04.2024

p.p. Christoph Bernads

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
48050	LARYVOX® Tape HYPOALLERGEN round
48100	LARYVOX® Tape STANDARD round
48120	LARYVOX® Tape FLEXIBLE round
48130	LARYVOX® Tape HYDROSOFT round
48140	LARYVOX® Tape COMFORT round
48150	LARYVOX® Tape HYPOALLERGEN oval
48200	LARYVOX® Tape STANDARD oval
48220	LARYVOX® Tape FLEXIBLE oval
48230	LARYVOX® Tape HYDROSOFT oval
48240	LARYVOX® Tape COMFORT oval
48250	LARYVOX® Tape HYPOALLERGEN XL oval
48300	LARYVOX® Tape STANDARD XL oval
48320	LARYVOX® Tape FLEXIBLE XL oval
48330	LARYVOX® Tape HYDROSOFT XL oval
48340	LARYVOX® Tape COMFORT XL oval
48500	LARYVOX® Tape CONVEX