

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 STYLE TOUCH
Basic UDI-DI	405194849820LVSTYTOU+ZBBX
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	1
Intended purpose	HME with speaking function. HMEs serve to humidify the airways and warm the air one breathes. HMEs filter the breathing air, thereby reducing intrusion of particles into the patient's airways.
Conformity assessment procedure	Medical devices are conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I. Conformity of medical devices is declared based on technical documentation according to EC regulation 2017/745 Annex II and III.

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.

Köln, 01.08.2022
Andreas Fahl Medizintechnik-Vertrieb GmbH


p.p. Christoph Bernads
Quality Management

EC Declaration of Conformity: TD_1.4_DOC_MDR_49820_Class_I_02
Annex: List of Medical Devices

Annex to EC Declaration of Conformity: TD_1.4_DOC_MDR_49820_Class_I_02

REF	Product name
49820-01	LARYVOX® STYLE CAP round blue metallic
49820-02	LARYVOX® STYLE CAP round gold
49820-03	LARYVOX® STYLE CAP round silver
49820-04	LARYVOX® STYLE CAP round beige
49820-90	LARYVOX® STYLE CAP round Set
49830-01	LARYVOX® STYLE TOP lamella blue metallic
49830-02	LARYVOX® STYLE TOP lamella gold
49830-03	LARYVOX® STYLE TOP lamella silver
49830-04	LARYVOX® STYLE TOP lamella beige
49830-90	LARYVOX® STYLE TOP lamella Set
49850-01	LARYVOX® TOUCH HME HighFlow blue metallic
49850-02	LARYVOX® TOUCH HME HighFlow gold
49850-03	LARYVOX® TOUCH HME HighFlow silver
49850-04	LARYVOX® TOUCH HME HighFlow beige
49850-13	LARYVOX® TOUCH HME HighFlow clear