

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 EXTRA HME
Basic UDI-DI	405194849860LVEXTRA+HMETD
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	1
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, 26.05.2021
Andreas Fahl Medizintechnik-Vertrieb GmbH


p.p. Christoph Bernads
Quality Management

EC Declaration of Conformity: TD_DOC_MDR_49860_Class_I_01
Annex: List of Medical Devices

Annex to EC Declaration of Conformity: TD_DOC_MDR_49860_Class_I_01

REF	Product name
49860	LARYVOX EXTRA HME
49860-xxyy	LARYVOX MY EXTRA HME
49861	LARYVOX EXTRA HME HighFlow
49861-xxyy	LARYVOX MY EXTRA HME HighFlow
49862	LARYVOX EXTRA HME Medium
49862-xxyy	LARYVOX MY EXTRA HME Medium
49863	LARYVOX EXTRA HME Sport
49863-xxyy	LARYVOX MY EXTRA HME Sport

xx – Farbcode Gehäuse / colour code housing

yy – Farbcode Deckel / colour code lid

10 – Gelb / Yellow	74 – Gold beige / Gold beige
20 – Orange / Orange	75 – Sand / Sand
30 – Rot / Red	76 – Creme / Cream
45 – Lila / Purple	77 – Honig / Honey
50 – Dunkelblau / Dark blue	78 – Karamell / Caramel
55 – Blau / Blue	79 – Dunkelbraun / Dark brown
60 – Grün / Green	80 – Braun / Brown
65 – Türkis / Turquoise	90 – Weiß / White
70 – Classic / Classic	95 – Schwarz / Black
71 – Vanille / Vanilla	98 – Gold / Gold
72 – Soft beige / Soft beige	99 – Silber / Silver
73 – Natur beige / Natural beige	