

### 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® HME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Basic UDI-DI                                    | 405194849800LV++++HME02AX                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Class acc. to EC regulation 2017/745 Annex VIII | Class IIa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Classification Rule                             | 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| REFs / Medical Devices                          | see annex on next page                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Intended purpose                                | HMEs serve to humidify the airways and warm the air one breathes. They reduce the formation of viscous secretions in the lungs and prevent the trachea from drying out. HMEs filter the breathing air, thereby reducing intrusion of particles into the patient's airways. The use of an HME creates the respiratory resistance that is necessary to maintain physiological lung function. Variants with an O2 connection also allow for the supply of additional oxygen.                              |
| Conformity assessment procedure                 | <p>Medical devices listed in the annex conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I.</p> <p>The conformity of medical devices is declared according to EC regulation 2017/745, Annex IX. Certificate No.: 1320GB448240228</p> <p>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.</p> |

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, 12.03.2025

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Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

### Annex to EC Declaration of Conformity: List of Medical Devices

| REF   | Medical Device           |
|-------|--------------------------|
| 49801 | LARYVOX® O2 Connect      |
| 49802 | LARYVOX® O2 HME          |
| 49803 | LARYVOX® O2 HME HighFlow |