

## 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 below 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 SIMPLY FIX
Basic UDI-DI	405194832680LVSIMFIX+VAGG
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	1
REF / Product name	32680 LARYVOX® SIMPLY FIX
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\_32680\_Class\_I\_01