ANDREAS FAHL
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EC Declaration of Conformity

The Company:

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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® SOS safe-mask
Basic UDI-DI	405194875000LVSOSSM++VACY
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	02
REF / Product name	see annex on next page
Intended purpose	Device for mouth-to-tracheostoma ventilation in emergency situations
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.

Köln, 31.03.2023
Andreas Fahl Medizintechnik-Vertrieb GmbH

C. Bernads

Christoph Bernads
Quality Management

EC Declaration of Conformity: TD_1.4_DOC_MDR_75000_Class_I_01
Annex: List of Medical Devices

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Annex to EC Declaration of Conformity: TD_1.4_DOC_MDR_75000_Class_I_01

REF	Product name
75000	LARYVOX® SOS safe-mask
75010	LARYVOX® SOS mask