ANDREAS FAHL
MEDIZINTECHNIK-VERTRIEB GMBH

August-Horch-Straße 4a
51149 Köln, Germany

Telefon +49(0)2203/2980-0
Telefax +49(0)2203/2980-100
mail vertrieb@fahl.de
www.fahl.de

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	Tracheosave®
Basic UDI-DI	4051948X20896PLATZHALTKNV
Class acc. to EC regulation 2017/745 Annex VIII	Class IIb
Classification Rule	5
REFs / Medical Devices	see annex on next page
Intended purpose	FAHL® tracheostomy tubes are intended to stabilise the tracheostomy following laryngectomy or tracheotomy. The tracheostomy tube is designed to keep the tracheostomy open. Tracheostomy tubes with cuff can be used for mechanical ventilation, including under anaesthesia. Percutec variants are designed for addi-tional use in percutaneous dilatation tracheostomy.
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 according to EC regulation 2017/745, Annex IX. Certificate No.: 1320GB448251015 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.

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, 15.10.2025

Andreas Fahl
Medizintechnik-Vertrieb GmbH

Christoph Bernads
Person Responsible for Regulatory Compliance

ANDREAS FAHL
MEDIZINTECHNIK-VERTRIEB GMBH

August-Horch-Straße 4a
51149 Köln, Germany

Telefon +49(0)2203/2980-0
Telefax +49(0)2203/2980-100
mail vertrieb@fahl.de
www.fahl.de

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
X20897	Tracheosave® Placeholder