

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	TRACHEOTEX®
Basic UDI-DI	405194840100TRACHTEX+TSLC
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	1
REFs / Medical Devices	see annex on next page
Intended purpose	TRACHEOTEX® are designed to be used for covering the tracheostoma and prevent the intrusion of foreign objects into the airways. At the same time, the breathing air is filtered, warmed and humidified, and escaping tracheal secretions are absorbed.
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.

Cologne, 16.05.2024

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Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
40100	TRACHEOTEX® BIB 3L
40110	TRACHEOTEX® BIB 3L PED
40200	TRACHEOTEX® BIB 5L
40210	TRACHEOTEX® BIB 5L PED
40300	TRACHEOTEX® BIB 8L
40400	TRACHEOTEX® BIB 12L
41600	TRACHEOTEX® BIB 16L
41700	TRACHEOTEX® Protection BIB large 21 x 19 cm
41700-BLACK	TRACHEOTEX® Protection BIB large 21 x 19 cm - BLACK
41800	TRACHEOTEX® Protection BIB small 15 x 12 cm
41800-BLACK	TRACHEOTEX® Protection BIB small 15 x 12 cm - BLACK
42000	TRACHEOTEX® Scarf
42002	TRACHEOTEX® EASY
42010	TRACHEOTEX® Scarf PED
43301	TRACHEOTEX® Shirt