

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, 04.04.2025

Andreas Fahl
Medizintechnik-Vertrieb GmbH

August-Horch-Straße 4a
D-51149 Köln (Pötz-Gremberghoven)

Christoph Bernads

(Person Responsible for Regulatory Compliance)

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
40100-86	Tracheotex® Bib 3L, beige
40110-81	Tracheotex® Bib 3L PED 24 - 33 cm, navy blue
40200-81	Tracheotex® BIB 5L, navy blue
40200-86	Tracheotex® Bib 5L, beige
40210-81	Tracheotex® Bib 5L PED 24 - 33 cm, navy blue
40300-86	Tracheotex® Bib 8L, beige
40400-86	Tracheotex® Bib 12L, beige
41600-D101	Tracheotex® Bib 16L, white
41600-D102	Tracheotex® Bib 16L, beige
41600-D103	Tracheotex® Bib 16L, light blue
41600-D104	Tracheotex® Bib 16L, dark blue
41600-D105	Tracheotex® Bib 16L, bordeaux red
41600-D106	Tracheotex® Bib 16L, black
41600-D107	Tracheotex® Bib 16L, brown
42000-001	Tracheotex® Scarf, white
42000-002	Tracheotex® Scarf, black
42000-003	Tracheotex® Scarf, silver-grey mottled
42000-004	Tracheotex® Scarf, beige
42000-009	Tracheotex® Scarf, marine
42000-010	Tracheotex® Scarf, light blue
42000-015	Tracheotex® Scarf, marine pattern
42000-016	Tracheotex® Scarf, black pattern
42000-018	Tracheotex® Scarf, bordeaux red
42000-026	Tracheotex® Scarf, brown
42000-063	Tracheotex® Scarf, light rosa
42000-067	Tracheotex® Scarf, blue gray
42000-068	Tracheotex® Scarf, aluminium gray
42000-069	Tracheotex® Scarf, silver-gray matte
42000-070	Tracheotex® Scarf, beige-sand
42000-071	Tracheotex® Scarf, dove blue
42000-072	Tracheotex® Scarf, pastel blue

REF	Medical Device
42000-467	Tracheotex® Scarf, pastel blue chequered
42000-468	Tracheotex® Scarf, blue chequered
42000-469	Tracheotex® Scarf, silver-gray chequered
42000-470	Tracheotex® Scarf, turquoise chequered
42000-471	Tracheotex® Scarf, beige-sand dotted
42000-472	Tracheotex® Scarf, silver-gray dotted
42000-473	Tracheotex® Scarf, graphite-gray dotted
42000-474	Tracheotex® Scarf, dark-brown dotted
42000-475	Tracheotex® Scarf, black dotted
42000-476	Tracheotex® Scarf, dark brown dotted
42002-731	Tracheotex® Easy, gray
42002-732	Tracheotex® Easy, dark red
42002-733	Tracheotex® Easy, blue-gray
42002-734	Tracheotex® Easy, gray-aluminium
42002-735	Tracheotex® Easy, silver-grey mottled
42002-737	Tracheotex® Easy, beige sand
42002-738	Tracheotex® Easy, pastel blue
42002-739	Tracheotex® Easy, pastel blue chequered
42002-740	Tracheotex® Easy, blue chequered
42002-741	Tracheotex® Easy, silvergray chequered
42002-742	Tracheotex® Easy, turquoise chequered
42002-743	Tracheotex® Easy, beige sand, white points
42002-744	Tracheotex® Easy, silvergray, white points
42002-745	Tracheotex® Easy, graphitgray, white points
42002-746	Tracheotex® Easy, darkbrown, white points
42002-747	Tracheotex® Easy, black, white big points
42002-748	Tracheotex® Easy, gray, white big points
42010-001	Tracheotex® Scarf PED, white
42010-010	Tracheotex® Scarf PED, light blue
42010-063	Tracheotex® Scarf PED, light pink
42010-071	Tracheotex® Scarf PED, pigeon blue
42010-072	Tracheotex® Scarf PED, turquoise

REF	Medical Device
42010-470	Tracheotex® Scarf PED, turquoise checkered
43001-900	Tracheotex® Rolli Klett Jersey, white
43001-901	Tracheotex® Rolli Klett Jersey, nature
43001-902	Tracheotex® Rolli Klett Jersey, light blue
43001-904	Tracheotex® Rolli Klett Jersey, navy blue
43001-905	Tracheotex® Rolli Klett Jersey, black
43001-906	Tracheotex® Rolli Klett Jersey, wine red
43001-907	Tracheotex® Rolli Klett Jersey, olive
43001-911	Tracheotex® Rolli Klett Jersey, mottled gray
43001-912	Tracheotex® Rolli Klett Jersey, bright red
43001-914	Tracheotex® Rolli Klett Jersey, dark brown
43301-900	Tracheotex® Shirt, white
43301-901	Tracheotex® Shirt, nature
43301-902	Tracheotex® Shirt, light blue
43301-904	Tracheotex® Shirt, navy blue
43301-905	Tracheotex® Shirt, black
43301-906	Tracheotex® Shirt, wine red
43301-907	Tracheotex® Shirt, olive
43301-911	Tracheotex® Shirt, mottled gray
43301-912	Tracheotex® Shirt, bright red
43301-914	Tracheotex® Shirt, dark brown