

### 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<br>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<br>procedure                 | <p>Medical devices listed in the annex conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I.</p> <p>The conformity of medical devices is declared based on technical documentation according to EC regulation 2017/745, Annex II and III.</p> <p>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.</p> |

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, 26.05.2025

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                               |
|------------|----------------------------------------------|
| 40100-00   | Tracheotex® Bib 3L, white                    |
| 40100-85   | Tracheotex® Bib 3L, black                    |
| 40100-86   | Tracheotex® Bib 3L, beige                    |
| 40110-81   | Tracheotex® Bib 3L PED 24 - 33 cm, navy blue |
| 40200-81   | Tracheotex® Bib 5L, navy blue                |
| 40200-85   | Tracheotex® Bib 5L, black                    |
| 40200-86   | Tracheotex® Bib 5L, beige                    |
| 40210-81   | Tracheotex® Bib 5L PED 24 - 33 cm, navy blue |
| 40300-85   | Tracheotex® Bib 8L, black                    |
| 40300-86   | Tracheotex® Bib 8L, beige                    |
| 40400-85   | Tracheotex® Bib 12L, black                   |
| 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 gray 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 pink                |
| 42000-067  | Tracheotex® Scarf, blue gray                 |

| REF       | Medical Device                                |
|-----------|-----------------------------------------------|
| 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                |
| 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, aluminium gray              |
| 42002-735 | Tracheotex® Easy, silver gray 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, silver gray chequered       |
| 42002-742 | Tracheotex® Easy, turquoise chequered         |
| 42002-743 | Tracheotex® Easy, beige sand, white points    |
| 42002-744 | Tracheotex® Easy, silver gray, white points   |
| 42002-745 | Tracheotex® Easy, graphite gray, white points |
| 42002-746 | Tracheotex® Easy, dark brown, white points    |
| 42002-747 | Tracheotex® Easy, black, white big points     |
| 42002-748 | Tracheotex® Easy, gray, white big points      |

| REF       | Medical Device                               |
|-----------|----------------------------------------------|
| 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             |
| 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                |