

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	TRACHEOSTOMA PROTECTION
Basic UDI-DI	405194845000TRACHFIX+TSN2
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	1
REFs / Medical Devices	see annex on next page
Intended purpose	Tracheostoma Protections filter the breathing air, thereby reducing intrusion of particles into the patient's airways. They store the moisture and warmth of the exhaled air in the filter medium and emit these to the inhaled air again during inspiration. We supply tracheostoma protections in different sizes. LARYNGOFIX® TOUCH / LARYTAPE® TOUCH enable closing the tracheostoma with a button and thus phonation.
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, 20.08.2024

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Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
45000	TRACHEOSTOMA-FIX® S, BEIGE 6,0 x 6,5 cm
45100	TRACHEOSTOMA-FIX® L, BEIGE 7,0 x 7,5 cm
45101	TRACHEOSTOMA-FIX® L, BEIGE 7,0 x 7,5 cm / 5 mm
45200	TRACHEOFIX® S, WHITE 5,5 x 6,0 cm
45300	TRACHEOFIX® L, WHITE 7,0 x 7,0 cm
45310	TRACHEOFIX® MINI, BEIGE 3,8 x 6,3 cm
45400	TRACHEOFIX® S, BEIGE 5,5 x 6,0 cm
45500	TRACHEOFIX® L, BEIGE 7,0 x 7,0 cm
45505	TRACHEOFIX® PLUS S, BEIGE 5,5 x 6,0 cm
45510	TRACHEOFIX® PLUS L, BEIGE 7,0 x 7,0 cm
45515	TRACHEOFIX® PLUS XL, beige 10,0 x 8,0 cm
45520	TRACHEOFIX® PRO, BEIGE 7,0 x 7,0 CM
45900	LARYNGOFIX® S, BEIGE 4,0 x 5,5 cm
45901	LARYNGOFIX® PRO S, BEIGE 4,0 x 5,5 cm / 5 mm
45902	LARYNGOFIX® PLUS S, BEIGE 4,0 x 5,5 cm
45905	LARYNGOFIX® S, WHITE 4,0 x 5,5 cm
45911	LARYNGOFIX® TOUCH L 4,8 x 6,7 cm
45950	LARYNGOFIX® L, BEIGE 4,8 x 6,7 cm
45952	LARYNGOFIX® PLUS L, BEIGE 4,8 x 6,7 cm
45955	LARYNGOFIX® L, WHITE 4,8 x 6,7 cm
45956	LARYNGOFIX® PRO L, BEIGE 4,8 x 6,7 cm / 5 mm
45960	LARYTAPE® S 4,0 x 5,5 cm
45962	LARYTAPE® L 4,8 x 6,7 cm
45963	LARYTAPE® XL 6,0 x 8,5 cm
45970	LARYTAPE® TOUCH S 4,0 x 5,5 cm
45972	LARYTAPE® TOUCH L 4,8 x 6,7 cm
45973	LARYTAPE® TOUCH XL 6,0 x 8,5 cm