

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	DURAVENT®
Basic UDI-DI	405194811000DURAVENT+ZBGT
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	2
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 additional 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 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
11990-05	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 5
11990-06	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 6
11990-07	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 7
11990-08	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 8
11990-09	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 9
11990-10	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 10
11990-11	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 11
11990-12	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 12
11990-13	DURAVENT® SOLO-ADAPTER KOMBI, SIZE 13
11992-05	DURAVENT® SOLO-ADAPTER UNI, SIZE 5
11992-06	DURAVENT® SOLO-ADAPTER UNI, SIZE 6
11992-07	DURAVENT® SOLO-ADAPTER UNI, SIZE 7
11992-08	DURAVENT® SOLO-ADAPTER UNI, SIZE 8
11992-09	DURAVENT® SOLO-ADAPTER UNI, SIZE 9
11992-10	DURAVENT® SOLO-ADAPTER UNI, SIZE 10
11992-11	DURAVENT® SOLO-ADAPTER UNI, SIZE 11
11992-12	DURAVENT® SOLO-ADAPTER UNI, SIZE 12
11992-13	DURAVENT® SOLO-ADAPTER UNI, SIZE 13
11995-05	DURAVENT® PLUG SIZE 5
11995-06	DURAVENT® PLUG SIZE 6
11995-07	DURAVENT® PLUG SIZE 7
11995-08	DURAVENT® PLUG SIZE 8
11995-09	DURAVENT® PLUG SIZE 9
11995-10	DURAVENT® PLUG SIZE 10
11995-11	DURAVENT® PLUG SIZE 11
11995-12	DURAVENT® PLUG SIZE 12
11995-13	DURAVENT® PLUG SIZE 13