

EC Declaration of Conformity

The Company:

Andreas Fahl Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4a
51149 Köln, Germany
SRN: DE-MF-00006665

hereby account for the medical devices listed in the annex on which this declaration is based, that they conform to the following EC directive:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)

Product group	X19201 - Duratwix®
Basic UDI-DI	405194819201DURATWIX+ST6D
Class acc. to Directive 93/42/EEC	Class Is
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 "essential requirements" of this directive as per Annex I. Conformity of the medical devices to Directive 93/42/EEC is declared as per Annex II. The manufacturer assumes sole responsibility for compliance with the requirements of Directive 93/42/EEC and all other Union legislation applicable to the medical devices listed in the annex below.

The manufacturer is subject to supervision by the notified body:
DNV MEDCERT GmbH (CE 0482), Pilatuspool 2, 20355 Hamburg, Germany

In accordance with Article 120 of the Medical Device Regulation (EU) 2017/745 (MDR), last amended by Regulation (EU) 2023/607, and MDCG 2020-3 Rev.1, the change of the covered products is considered a non-significant change.

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

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Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
X19805	Duratwix® Plug
X19806	Duratwix® Solo-Adapter Uni
X19807	Duratwix® Solo-Adapter Vario
X19808	Duratwix® Solo-Adapter Kombi