

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 directive:

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

Product group	Humido
Basic UDI-DI	0405194846440HUMIDOFXHME8Q
Class acc. to Directive 93/42/EEC	Class Is
Classification Rule	02
REFs / Medical Devices	see annex on next page
Intended purpose	HMEs serve to humidify the airways and warm the air one breathes. They reduce the formation of viscous secretions in the lungs and prevent the trachea from drying out. HMEs filter the breathing air, thereby reducing intrusion of particles into the patient's airways. The use of an HME creates the respiratory resistance that is necessary to maintain physiological lung function. Variants with an O2 connection also allow for the supply of additional oxygen.
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, 26.08.2024

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Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
46440	HUMIDOFIX® 15 mm