

EC Declaration of Conformity

The Company:

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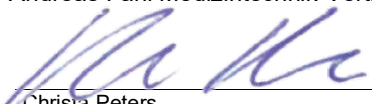
hereby account for the medical devices listed in the annex on which this declaration is based, that they conform to the following EC legislation:

Regulation (EC) 2017/745 of 05 April 2017, Medical Device Regulation (MDR)

Product group	HUMIDO
Basic UDI-DI	405194846150HUMIDO++HMEKB
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	01
REF / Product name	see annex on next page
Intended purpose	HMEs serve to humidify the airways and warm the inhaled air. They reduce the formation of viscous secretions in the lungs and prevent the trachea from drying out. The HMEs filter the air and thus reduce the penetration of particles into the patient's airways. The use of an HME creates a breathing resistance that is necessary to maintain physiologic pulmonary function.
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.

Köln, 04.04.2023
Andreas Fahl Medizintechnik-Vertrieb GmbH


Christa Peters
Quality Management

EC Declaration of Conformity: TD_1.4_DOC_MDR_46150_Class_I_04
Annex: List of Medical Devices

Annex to EC Declaration of Conformity: TD_1.4_DOC_MDR_46150_Class_I_04

REF	Product name
46160	HUMIDOSTOM®
46460	HUMIDOTWIN®
46850	HUMIDOSTOM® JUNIOR