

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	Tube Holder 7000331
Basic UDI-DI	405194832553TH7000331KBZC
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	1
REF / Product name	see annex on next page
Intended purpose	Tube holders are used to fix and secure tracheostomy tubes in the tracheostoma of tracheotomised or laryngectomised patients.
Conformity assessment procedure	Medical devices are conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I. Conformity of medical devices is declared based on technical documentation according to EC regulation 2017/745 Annex II and III.

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, 28.02.2023
Andreas Fahl Medizintechnik-Vertrieb GmbH



Christa Peters
Quality Management

EC Declaration of Conformity: TD_1.4_DOC_MDR_32553_Class_I_01

Annex to EC Declaration of Conformity: TD_1.4_DOC_MDR_32553_Class_I_01

REF	Product name
32553	OPTIFLAUSCH® K beige 24 - 45 cm
32555	OPTIFLAUSCH® K PED 16 - 25 cm