

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 71706
Basic UDI-DI	405194832000TH71706++KBKE
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	1
REF / Product name	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, 18.01.2023
Andreas Fahl Medizintechnik-Vertrieb GmbH

Andreas Fahl
Medizintechnik-Vertrieb GmbH
(August-Horch-Straße 4a
D-51149 Köln (Post-Gemeindegebiet))
p.p. Christoph Bernads
Quality Management

EC Declaration of Conformity: TD_1.4_DOC_MDR_32000_Class_I_02
Annex: List of Medical Devices

Annex to EC Declaration of Conformity: TD_1.4_DOC_MDR_32000_Class_I_02

REF	Product name
32000	KACLIP® HM beige, 30 - 50 cm
32001	KACLIP® HM PED, 13 - 25 cm
32005	KACLIP® H beige, 30 - 50 cm
32005-02	KACLIP® H white, 30 - 50 cm
32005-03	KACLIP® H beige (with broad hooks)
32005-04	KACLIP® H white (with broad hooks)
32010	KACLIP® K white, 30 - 50 cm
32011	KACLIP® K beige, 30 - 50cm
32015	KACLIP® Clear H, 29 - 52 cm
32300	SUPRAPHIX® 25 H, 35 - 42 cm
32301	SUPRAPHIX® 18 H, 22 - 41 cm
32303	SUPRAPHIX® 36 H, 40 - 58 cm
32305	SUPRAPHIX® 30 H, 34 - 54 cm
32308	SUPRAPHIX® 11 H PED, 15 - 26 cm
32310	SUPRAPHIX® 13 H PED, 17 - 28 cm
32311	SUPRAPHIX® 15 H PED, 19 - 30 cm
32500	SUPRAPHIX® 25 K, 32 - 48 cm
32501	SUPRAPHIX® 30 K, 37 - 53 cm
32502	SUPRAPHIX® 18 K, 20 - 40 cm
32503	SUPRAPHIX® 36 K, 43 - 57 cm
32509	SUPRAPHIX® 11 K PED, 18 - 25 cm
32510	SUPRAPHIX® 13 K PED, 20 - 27 cm
32512	SUPRAPHIX® 15 K PED, 22 - 29 cm
32550	OPTIFLAUSCH® K, 24 - 45 cm
32551	OPTIFLAUSCH® H, 24 - 47 cm

REF	Product name
32552	OPTIFLAUSCH® Slim K, 24 - 42 cm
32556	OPTIFLAUSCH® K Junior PED, 16 - 25cm
32557	OPTIFLAUSCH® Slim K PED, 16 - 30 cm
32558	OPTIFLAUSCH® Slim K Junior PED, 16 – 30 cm
32610	NECKFIX® Blue K, 45 cm
32612	NECKFIX® Blue PED K, 34 cm
32615	NECKFIX® Endo, 85 cm
32620	NECKFIX® K, 45 cm
32621	NECKFIX® Beige K PED, 34 cm
32622	NECKFIX® Beige K, 46 cm
32623	NECKFIX® Beige K XL, 50 cm
32629	NECKFIX® DUO PLUS K
32630	NECKFIX® Duo K, 40 - 53 cm
32631	NECKFIX® Duo K Beige, 40 - 53 cm