

EC Declaration of Conformity

The Company:

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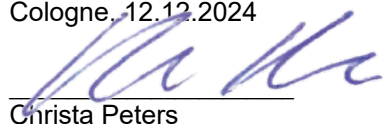
hereby account for the medical devices listed in the annex on which this declaration is based, that they conform to the following EC legislation:

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

Product group	32000 - Tube Holder 7000494
Basic UDI-DI	405194832000TH7000494KBJV
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	1
REFs / Medical Devices	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 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.

Cologne, 12.12.2024



Christa Peters

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
32000	KACLIP® HM beige 30 - 50 cm
32001	KACLIP® HM PED 13 - 25 cm
32004	KACLIP® Kanülentrageband mit Haken für Kinder, hautfarben
32005	KACLIP® H beige 30 - 50 cm
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
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
32552	OPTIFLAUSCH® Slim K 24 - 42 cm
32553	OPTIFLAUSCH® K beige 24 - 45 cm
32555	OPTIFLAUSCH® K PED 16 - 25 cm
32556	OPTIFLAUSCH® K Junior PED 16-25cm
32557	OPTIFLAUSCH® Slim K PED 16 - 30 cm
32558	OPTIFLAUSCH® Slim K Junior PED 16-30cm
32559	OPTIFLAUSCH® H beige 24 - 47 cm
32610	NECKFIX® Blue K 45 cm

REF	Medical Device
32612	NECKFIX® Blue PED K 34 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 K PLUS
32630	NECKFIX® Duo K 40-53 cm
32631	NECKFIX® Duo K beige 40 - 53 cm
32000-SHW	KACLIP® Kanülentrageband mit Metall-Haken, hautfarben, SA
32005-02	KACLIP® H white 30 - 50 cm
32005-03	KACLIP® H beige (mit breiten Haken / with broad hooks)
32005-04	KACLIP® H white (mit breiten Haken / with broad hooks)
32502-10	SUPRAFIX® 18 K 20 - 40 cm
32550-100	OPTIFLAUSCH® K 24 - 45 cm
32550-60	Optiflausch Kanülentrageband mit Klettverschluss
32551-100	Optiflausch Kanülentrageband mit Kunststoff-Haken
32629-01	NECKFIX® DUO K PLUS
32629-K	NECKFIX® DUO K PLUS