ANDREAS FAHL
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EC Declaration of Conformity

The Company:

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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	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, 12.02.2025

Christa Peters

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

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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
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	SUPRAFIX® 25 H 35 - 42 cm
32301	SUPRAFIX® 18 H 22 - 41 cm
32303	SUPRAFIX® 36 H 40 - 58 cm
32305	SUPRAFIX® 30 H 34 - 54 cm
32308	SUPRAFIX® 11 H PED
32310	SUPRAFIX® 13 H PED 17 - 28 cm
32311	SUPRAFIX® 15 H PED 19 - 30 cm
32500	SUPRAFIX® 25 K 32 - 48 cm
32501	SUPRAFIX® 30 K 37 - 53 cm
32502	SUPRAFIX® 18 K 20 - 40 cm
32503	SUPRAFIX® 36 K 43 - 57 cm
32509	SUPRAFIX® 11 K PED 18 - 25 cm
32510	SUPRAFIX® 13 K PED 20 - 27 cm
32512	SUPRAFIX® 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
32612	NECKFIX® Blue PED K 34 cm

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REF	Medical Device
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
32005-02	KACLIP® H white 30 - 50 cm
32005-03	KACLIP® H beige with broad hooks
32005-04	KACLIP® H white with broad hooks
32502-10	SUPRAFIX® 18 K 20 - 40 cm
32550-100	OPTIFLAUSCH® K 24 - 45 cm
32551-100	OPTIFLAUSCH® H 24 - 47 cm
32629-01	NECKFIX® DUO K PLUS
32629-K	NECKFIX® DUO K PLUS