

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	NECKFIX® Endo
Basic UDI-DI	405194832613NCKFXENDOKBTC
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	1
REFs / Medical Devices	see annex on next page
Intended purpose	NECKFIX® Endo is used to secure endotracheal tubes (oral/nasal), double lumen tubes, laryngeal tubes and laryngeal masks.
Conformity assessment procedure	<p>Medical devices listed in the annex conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I.</p> <p>The conformity of medical devices is declared based on technical documentation according to EC regulation 2017/745, Annex II and III.</p> <p>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.</p>

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, 03.06.2024



Christa Peters

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
32613	NECKFIX® Endo, 85 cm
32614	NECKFIX® Endo, 72 cm
32615	NECKFIX® Endo Safety K, 85 cm
32616	NECKFIX® Endo Safety K, 72 cm
32617	NECKFIX® Endo Velcro Strips
32920	NECKFIX® Endo PRO Set, 28 cm Pad with Adhesive Strip and Velcro + Neck Pad 32,5 cm
32921	NECKFIX® Endo PRO, 28 cm Pad with Adhesive Strip and Velcro
32931	NECKFIX® Endo PRO Neck Pad L 32,5 cm
32932	NECKFIX® Endo PRO Neck Pad XL 47 cm
32940	NECKFIX® Endo Lock-Set, 28cm Pad with Adhesive Strip and 2 Fixing Plasters
32945	NECKFIX® Endo Lock Fixing Plasters
32940-M28	NECKFIX® Endo Lock, 28cm Pad with Adhesive Strip