

### 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	30400 - Tracheal Compresses 70053
Basic UDI-DI	405194830625TC70053++KPRW
Class acc. to EC regulation 2017/745 Annex VIII	Class Is
Classification Rule	4
REFs / Medical Devices	see annex on next page
Intended purpose	Tracheal compresses serve to absorb tracheal secretions and to cushion the tracheal neck flange against the skin.
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 according to EC regulation 2017/745, Annex IX. Certificate No.: 1320GB448251015</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>

The manufacturer is subject to supervision by the notified body:  
**DNV MEDCERT GmbH (CE 0482), Pilatuspool 2, 20355 Hamburg, Germany**

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, 15.10.2025

Andreas Fahl  
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August-Horch-Straße 4a  
51149 Köln, Germany

Christoph Bernads

Person Responsible for Regulatory Compliance

## Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
30606	2-KAM® SLIT, sterile 9x9,8cm
30625	2-KAM® SLIT INTENSIVE 9x9,8cm