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EC Declaration of Conformity

The Company:

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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	405194830400TC70053++KPEV
Class acc. to EC regulation 2017/745 Annex VIII	Class I
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	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

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Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
30400	1-KAM® 9x9,8cm
30500	1-KAM® SLIT 9x9,8cm
30551	1-KAM ALULINE® ZIP, 9 x 9.8 cm
30600	2-KAM® 9x9,8cm
30601	2-KAM® SLIT 9x9,8cm
30606	2-KAM® SLIT, sterile 9x9,8cm
30610	1-KAM® PED 6x7cm
30620	1-KAM® PED SLIT 6x7cm
30631	2-KAM® MINI 6 x 7cm
30640	2-KAM® PED SLIT 6x7cm
30700	3-KAM® 10x14cm
30701	3-KAM® SLIT 10x14cm
30400-NE	1-KAM® Tracheal-Kompresse, 9x9,8cm, neutral
30500-NE	1-KAM Tracheal-Kompresse, geschlitzt, 9x9,8cm
30600-NE	2-KAM Zweikammer-Tracheal- Kompresse, 9x9,8cm, neutral