ANDREAS FAHL
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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	TRACHEAL COMPRESSES
Basic UDI-DI	405194830400TRACHB+++KPU3
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	1
Conformity assessment procedure	Medical devices are conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I. Conformity of medical devices is declared based on technical documentation according to EC regulation 2017/745 Annex II and III.

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.

Köln, 26.05.2021
Andreas Fahl Medizintechnik-Vertrieb GmbH

C. Bernads

p.p. Christoph Bernads
Quality Management

EC Declaration of Conformity: TD_DOC_MDR_30400_Class_I_01
Annex: List of Medical Devices

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Annex to EC Declaration of Conformity: TD_DOC_MDR_30400_Class_I_01

REF	Product name
30400	1-KAM®, 9 x 9.8 cm
30500	1-KAM® SLIT, 9 x 9.8 cm
30600	2-KAM®, 9 x 9.8 cm
30601	2-KAM® SLIT, 9 x 9,8 cm
30610	1-KAM® PED, 6 x 7 cm
30620	1-KAM® PED SLIT, 6 x 7 cm
30631	2-KAM® MINI, 7,2 x 6 cm
30640	2-KAM® PED SLIT, 6 x 7 cm
30700	3-KAM®, 10 x 14 cm
30701	3-KAM® SLIT, 10 x 14 cm