ANDREAS FAHL
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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	FAHL DECANNULATION TAPE
Basic UDI-DI	405194848000DEC++++++TA4L
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Rule	1
REF / Product name	Siehe nächste Seite / see next page
Zweckbestimmung / Intended purpose	Die Dekanülierungspflaster mit Cuff dienen zur vorübergehenden und sicheren Abdichtung des Tracheostomas bei tracheotomierten Patienten. / The decannulation patches with cuff are used for temporary and secure sealing of the tracheostoma in tracheotomized patients.
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, 07.07.2022
Andreas Fahl Medizintechnik-Vertrieb GmbH

i.A. Schwerdt

p.p. Thomas Schwerdt
Quality Management

EC Declaration of Conformity: TD_1.4_DOC_MDR_48000_Class_I_02
Annex: List of Medical Devices

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Annex to EC Declaration of Conformity: TD_1.4_DOC_MDR_48000_Class_I_02

REF	Product name
48000-01	FAHL® DECANNULATION TAPE COMFORT LARGE
48000-02	FAHL® DECANNULATION TAPE COMFORT SMALL
48000-03	FAHL® DECANNULATION TAPE COMFORT OVAL
48001-01	FAHL® DECANNULATION TAPE FLEXIBLE LARGE
48001-02	FAHL® DECANNULATION TAPE FLEXIBLE SMALL
48001-03	FAHL® DECANNULATION TAPE FLEXIBLE OVAL