

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 directive:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)

Product group	DURACUFF®
Basic UDI-DI	405194813000DURACUFF+TKAC
Class acc. to Directive 93/42/EEC	Class IIb
Classification Rule	5
REFs / Medical Devices	see annex on next page
Intended purpose	FAHL® tracheostomy tubes are intended to stabilise the tracheostomy following laryngectomy or tracheotomy. The tracheostomy tube is designed to keep the tracheostomy open. Tracheostomy tubes with cuff can be used for mechanical ventilation, including under anaesthesia. Percutec variants are designed for additional use in percutaneous dilatation tracheostomy.
Conformity assessment procedure	Medical devices listed in the annex conform to "essential requirements" of this directive as per Annex I. Conformity of the medical devices to Directive 93/42/EEC is declared as per Annex II. The manufacturer assumes sole responsibility for compliance with the requirements of Directive 93/42/EEC and all other Union legislation applicable to the medical devices listed in the annex below.

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, 27.05.2024

Andreas Fahl
Medizintechnik-Vertrieb GmbH
(August-Horch-Straße 4a
D-51149 Köln (Pulch-Gembarhoven))
Telefon: +49 (0) 2203 / 29 80 - 0
Telefax: +49 (0) 2203 / 29 80 - 100

p.p. Christoph Bernads

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
13000-07	DURACUFF® VARIO SIZE 7
13000-08	DURACUFF® VARIO SIZE 8
13000-09	DURACUFF® VARIO SIZE 9
13000-10	DURACUFF® VARIO SIZE 10
13000-11	DURACUFF® VARIO SIZE 11
13000-12	DURACUFF® VARIO SIZE 12
13002-07	DURACUFF® UNI-VARIO 1 ICU + 1 ICV, SIZE 7
13002-08	DURACUFF® UNI-VARIO 1 ICU + 1 ICV, SIZE 8
13002-09	DURACUFF® UNI-VARIO 1 ICU + 1 ICV, SIZE 9
13002-10	DURACUFF® UNI-VARIO 1 ICU + 1 ICV, SIZE 10
13002-11	DURACUFF® UNI-VARIO 1 ICU + 1 ICV, SIZE 11
13002-12	DURACUFF® UNI-VARIO 1 ICU + 1 ICV, SIZE 12
13003-07	DURACUFF® VARIO 2 ICV, SIZE 7
13003-08	DURACUFF® VARIO 2 ICV, SIZE 8
13003-09	DURACUFF® VARIO 2 ICV, SIZE 9
13003-10	DURACUFF® VARIO 2 ICV, SIZE 10
13003-11	DURACUFF® VARIO 2 ICV, SIZE 11
13003-12	DURACUFF® VARIO 2 ICV, SIZE 12
13012-07	DURACUFF® VARIO-KOMBI LINGO PHON 1 ICV + 1 ICFK + 1CP, SIZE 7
13012-08	DURACUFF® VARIO-KOMBI LINGO PHON 1 ICV + 1 ICFK + 1CP, SIZE 8
13012-09	DURACUFF® VARIO-KOMBI LINGO PHON 1 ICV + 1 ICFK + 1CP, SIZE 9
13012-10	DURACUFF® VARIO-KOMBI LINGO PHON 1 ICV + 1 ICFK + 1CP, SIZE 10
13012-11	DURACUFF® VARIO-KOMBI LINGO PHON 1 ICV + 1 ICFK + 1CP, SIZE 11
13012-12	DURACUFF® VARIO-KOMBI LINGO PHON 1 ICV + 1 ICFK + 1CP, SIZE 12
13022-07	DURACUFF® UNI-VARIO LINGO 1 ICV + 1 ICFU, SIZE 7
13022-08	DURACUFF® UNI-VARIO LINGO 1 ICV + 1 ICFU, SIZE 8
13022-09	DURACUFF® UNI-VARIO LINGO 1 ICV + 1 ICFU, SIZE 9
13022-10	DURACUFF® UNI-VARIO LINGO 1 ICV + 1 ICFU, SIZE 10
13022-11	DURACUFF® UNI-VARIO LINGO 1 ICV + 1 ICFU, SIZE 11
13022-12	DURACUFF® UNI-VARIO LINGO 1 ICV + 1 ICFU, SIZE 12
13032-07	DURACUFF® UNI-VARIO SUCTION 1 ICU + 1 ICV, SIZE 7

REF	Medical Device
13032-08	DURACUFF® UNI-VARIO SUCTION 1 ICU + 1 ICV, SIZE 8
13032-09	DURACUFF® UNI-VARIO SUCTION 1 ICU + 1 ICV, SIZE 9
13032-10	DURACUFF® UNI-VARIO SUCTION 1 ICU + 1 ICV, SIZE 10
13032-11	DURACUFF® UNI-VARIO SUCTION 1 ICU + 1 ICV, SIZE 11
13032-12	DURACUFF® UNI-VARIO SUCTION 1 ICU + 1 ICV, SIZE 12
13040-07	DURACUFF® VARIO SUCTION, SIZE 7
13040-08	DURACUFF® VARIO SUCTION, SIZE 8
13040-09	DURACUFF® VARIO SUCTION, SIZE 9
13040-10	DURACUFF® VARIO SUCTION, SIZE 10
13040-11	DURACUFF® VARIO SUCTION, SIZE 11
13040-12	DURACUFF® VARIO SUCTION, SIZE 12
13042-07	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION 1ICV+1ICFK+1CP,SIZE 7
13042-08	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION 1ICV+1ICFK+1CP,SIZE 8
13042-09	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION 1ICV+1ICFK+1CP,SIZE 9
13042-10	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION 1ICV+1ICFK+1CP,SIZE 10
13042-11	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION 1ICV+1ICFK+1CP,SIZE 11
13042-12	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION 1ICV+1ICFK+1CP,SIZE 12
13072-07	DURACUFF® VARIO-KOMBI LINGO 1 ICV + 1 ICFK, SIZE 7
13072-08	DURACUFF® VARIO-KOMBI LINGO 1 ICV + 1 ICFK, SIZE 8
13072-09	DURACUFF® VARIO-KOMBI LINGO 1 ICV + 1 ICFK, SIZE 9
13072-10	DURACUFF® VARIO-KOMBI LINGO 1 ICV + 1 ICFK, SIZE 10
13072-11	DURACUFF® VARIO-KOMBI LINGO 1 ICV + 1 ICFK, SIZE 11
13072-12	DURACUFF® VARIO-KOMBI LINGO 1 ICV + 1 ICFK, SIZE 12
13100-07	DURACUFF® VARIO M SIZE 7
13100-08	DURACUFF® VARIO M SIZE 8
13100-09	DURACUFF® VARIO M SIZE 9
13100-10	DURACUFF® VARIO M SIZE 10
13100-11	DURACUFF® VARIO M SIZE 11
13100-12	DURACUFF® VARIO M SIZE 12
13102-07	DURACUFF® UNI-VARIO M 1 ICU + 1 ICV, SIZE 7
13102-08	DURACUFF® UNI-VARIO M 1 ICU + 1 ICV, SIZE 8
13102-09	DURACUFF® UNI-VARIO M 1 ICU + 1 ICV, SIZE 9

REF	Medical Device
13102-10	DURACUFF® UNI-VARIO M 1 ICU + 1 ICV, SIZE 10
13102-11	DURACUFF® UNI-VARIO M 1 ICU + 1 ICV, SIZE 11
13102-12	DURACUFF® UNI-VARIO M 1 ICU + 1 ICV, SIZE 12
13103-07	DURACUFF® VARIO M 2 ICV, SIZE 7
13103-08	DURACUFF® VARIO M 2 ICV, SIZE 8
13103-09	DURACUFF® VARIO M 2 ICV, SIZE 9
13103-10	DURACUFF® VARIO M 2 ICV, SIZE 10
13103-11	DURACUFF® VARIO M 2 ICV, SIZE 11
13103-12	DURACUFF® VARIO M 2 ICV, SIZE 12
13112-07	DURACUFF® VARIO-KOMBI LINGO PHON M, 1 ICV + 1 ICFK + 1CP, SIZE 7
13112-08	DURACUFF® VARIO-KOMBI LINGO PHON M, 1 ICV + 1 ICFK + 1CP, SIZE 8
13112-09	DURACUFF® VARIO-KOMBI LINGO PHON M, 1 ICV + 1 ICFK + 1CP, SIZE 9
13112-10	DURACUFF® VARIO-KOMBI LINGO PHON M, 1 ICV + 1 ICFK + 1CP, SIZE 10
13112-11	DURACUFF® VARIO-KOMBI LINGO PHON M, 1 ICV + 1 ICFK + 1CP, SIZE 11
13112-12	DURACUFF® VARIO-KOMBI LINGO PHON M, 1 ICV + 1 ICFK + 1CP, SIZE 12
13122-07	DURACUFF® UNI-VARIO LINGO M 1 ICV + 1 ICFU, SIZE 7
13122-08	DURACUFF® UNI-VARIO LINGO M 1 ICV + 1 ICFU, SIZE 8
13122-09	DURACUFF® UNI-VARIO LINGO M 1 ICV + 1 ICFU, SIZE 9
13122-10	DURACUFF® UNI-VARIO LINGO M 1 ICV + 1 ICFU, SIZE 10
13122-11	DURACUFF® UNI-VARIO LINGO M 1 ICV + 1 ICFU, SIZE 11
13122-12	DURACUFF® UNI-VARIO LINGO M 1 ICV + 1 ICFU, SIZE 12
13132-07	DURACUFF® UNI-VARIO SUCTION M 1 ICU + 1 ICV, SIZE 7
13132-08	DURACUFF® UNI-VARIO SUCTION M 1 ICU + 1 ICV, SIZE 8
13132-09	DURACUFF® UNI-VARIO SUCTION M 1 ICU + 1 ICV, SIZE 9
13132-10	DURACUFF® UNI-VARIO SUCTION M 1 ICU + 1 ICV, SIZE 10
13132-11	DURACUFF® UNI-VARIO SUCTION M 1 ICU + 1 ICV, SIZE 11
13132-12	DURACUFF® UNI-VARIO SUCTION M 1 ICU + 1 ICV, SIZE 12
13140-07	DURACUFF® VARIO SUCTION M, SIZE 7
13140-08	DURACUFF® VARIO SUCTION M, SIZE 8
13140-09	DURACUFF® VARIO SUCTION M, SIZE 9
13140-10	DURACUFF® VARIO SUCTION M, SIZE 10
13140-11	DURACUFF® VARIO SUCTION M, SIZE 11

REF	Medical Device
13140-12	DURACUFF® VARIO SUCTION M, SIZE 12
13142-07	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION M,1 ICV +1 ICFK +1 CP, SIZE 7
13142-08	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION M,1 ICV +1 ICFK +1 CP, SIZE 8
13142-09	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION M,1 ICV +1 ICFK +1 CP, SIZE 9
13142-10	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION M,1 ICV +1 ICFK +1 CP, SIZE 10
13142-11	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION M,1 ICV +1 ICFK +1 CP, SIZE 11
13142-12	DURACUFF® VARIO-KOMBI LINGO PHON SUCTION M,1 ICV +1 ICFK +1 CP, SIZE 12
13172-07	DURACUFF® VARIO-KOMBI LINGO M 1 ICV + 1 ICFK, SIZE 7
13172-08	DURACUFF® VARIO-KOMBI LINGO M 1 ICV + 1 ICFK, SIZE 8
13172-09	DURACUFF® VARIO-KOMBI LINGO M 1 ICV + 1 ICFK, SIZE 9
13172-10	DURACUFF® VARIO-KOMBI LINGO M 1 ICV + 1 ICFK, SIZE 10
13172-11	DURACUFF® VARIO-KOMBI LINGO M 1 ICV + 1 ICFK, SIZE 11
13172-12	DURACUFF® VARIO-KOMBI LINGO M 1 ICV + 1 ICFK, SIZE 12
13200-07	DURACUFF® VARIO XL SIZE 7
13200-08	DURACUFF® VARIO XL SIZE 8
13200-09	DURACUFF® VARIO XL SIZE 9
13200-10	DURACUFF® VARIO XL SIZE 10
13200-11	DURACUFF® VARIO XL SIZE 11
13200-12	DURACUFF® VARIO XL SIZE 12
13202-07	DURACUFF® UNI-VARIO XL 1 ICU + 1 ICV, SIZE 7
13202-08	DURACUFF® UNI-VARIO XL 1 ICU + 1 ICV, SIZE 8
13202-09	DURACUFF® UNI-VARIO XL 1 ICU + 1 ICV, SIZE 9
13202-10	DURACUFF® UNI-VARIO XL 1 ICU + 1 ICV, SIZE 10
13202-11	DURACUFF® UNI-VARIO XL 1 ICU + 1 ICV, SIZE 11
13202-12	DURACUFF® UNI-VARIO XL 1 ICU + 1 ICV, SIZE 12
13203-07	DURACUFF® VARIO XL 2 ICV, SIZE 7
13203-08	DURACUFF® VARIO XL 2 ICV, SIZE 8
13203-09	DURACUFF® VARIO XL 2 ICV, SIZE 9
13203-10	DURACUFF® VARIO XL 2 ICV, SIZE 10
13203-11	DURACUFF® VARIO XL 2 ICV, SIZE 11
13203-12	DURACUFF® VARIO XL 2 ICV, SIZE 12
13212-07	DURACUFF® VARIO-KOMBI LINGO PHON XL, 1 ICV + 1 ICFK + 1CP, SIZE 7

REF	Medical Device
13212-08	DURACUFF® VARIO-KOMBI LINGO PHON XL, 1 ICV + 1 ICFK + 1CP, SIZE 8
13212-09	DURACUFF® VARIO-KOMBI LINGO PHON XL, 1 ICV + 1 ICFK + 1CP, SIZE 9
13212-10	DURACUFF® VARIO-KOMBI LINGO PHON XL, 1 ICV + 1 ICFK + 1CP, SIZE 10
13212-11	DURACUFF® VARIO-KOMBI LINGO PHON XL, 1 ICV + 1 ICFK + 1CP, SIZE 11
13212-12	DURACUFF® VARIO-KOMBI LINGO PHON XL, 1 ICV + 1 ICFK + 1CP, SIZE 12
13222-07	DURACUFF® UNI-VARIO LINGO XL 1 ICV + 1 ICFU, SIZE 7
13222-08	DURACUFF® UNI-VARIO LINGO XL 1 ICV + 1 ICFU, SIZE 8
13222-09	DURACUFF® UNI-VARIO LINGO XL 1 ICV + 1 ICFU, SIZE 9
13222-10	DURACUFF® UNI-VARIO LINGO XL 1 ICV + 1 ICFU, SIZE 10
13222-11	DURACUFF® UNI-VARIO LINGO XL 1 ICV + 1 ICFU, SIZE 11
13222-12	DURACUFF® UNI-VARIO LINGO XL 1 ICV + 1 ICFU, SIZE 12
13232-07	DURACUFF® UNI-VARIO SUCTION XL 1 ICU + 1 ICV, SIZE 7
13232-08	DURACUFF® UNI-VARIO SUCTION XL 1 ICU + 1 ICV, SIZE 8
13232-09	DURACUFF® UNI-VARIO SUCTION XL 1 ICU + 1 ICV, SIZE 9
13232-10	DURACUFF® UNI-VARIO SUCTION XL 1 ICU + 1 ICV, SIZE 10
13232-11	DURACUFF® UNI-VARIO SUCTION XL 1 ICU + 1 ICV, SIZE 11
13232-12	DURACUFF® UNI-VARIO SUCTION XL 1 ICU + 1 ICV, SIZE 12
13240-07	DURACUFF® VARIO SUCTION XL, SIZE 7
13240-08	DURACUFF® VARIO SUCTION XL, SIZE 8
13240-09	DURACUFF® VARIO SUCTION XL, SIZE 9
13240-10	DURACUFF® VARIO SUCTION XL, SIZE 10
13240-11	DURACUFF® VARIO SUCTION XL, SIZE 11
13240-12	DURACUFF® VARIO SUCTION XL, SIZE 12
13242-07	DURACUFF® VARIO-KOMBI LINGO-PHON SUCTION XL, 1 ICV + 1 ICFK + 1 COMBIPHON®, SIZE 7
13242-08	DURACUFF® VARIO-KOMBI LINGO-PHON SUCTION XL, 1 ICV + 1 ICFK + 1 COMBIPHON®, SIZE 8
13242-09	DURACUFF® VARIO-KOMBI LINGO-PHON SUCTION XL, 1 ICV + 1 ICFK + 1 COMBIPHON®, SIZE 9
13242-10	DURACUFF® VARIO-KOMBI LINGO-PHON SUCTION XL, 1 ICV + 1 ICFK + 1 COMBIPHON®, SIZE 10
13242-11	DURACUFF® VARIO-KOMBI LINGO-PHON SUCTION XL, 1 ICV + 1 ICFK + 1 COMBIPHON®, SIZE 11
13242-12	DURACUFF® VARIO-KOMBI LINGO-PHON SUCTION XL, 1 ICV + 1 ICFK + 1 COMBIPHON®, SIZE 12
13272-07	DURACUFF® VARIO-KOMBI LINGO XL 1 ICV + 1 ICFK, SIZE 7
13272-08	DURACUFF® VARIO-KOMBI LINGO XL 1 ICV + 1 ICFK, SIZE 8
13272-09	DURACUFF® VARIO-KOMBI LINGO XL 1 ICV + 1 ICFK, SIZE 9

REF	Medical Device
13272-10	DURACUFF® VARIO-KOMBI LINGO XL 1 ICV + 1 ICFK, SIZE 10
13272-11	DURACUFF® VARIO-KOMBI LINGO XL 1 ICV + 1 ICFK, SIZE 11
13272-12	DURACUFF® VARIO-KOMBI LINGO XL 1 ICV + 1 ICFK, SIZE 12