

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	DURAVENT®
Basic UDI-DI	405194811000DURAVENT+TKGT
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
51149 Köln, Germany
p.p. Christoph Bernads
Telefax: +49 (0) 2203 / 29 80 - 100

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
11000-03	DURAVENT® SIZE 3
11000-04	DURAVENT® SIZE 4
11000-05	DURAVENT® SIZE 5
11000-06	DURAVENT® SIZE 6
11000-07	DURAVENT® SIZE 7
11000-08	DURAVENT® SIZE 8
11000-09	DURAVENT® SIZE 9
11000-10	DURAVENT® SIZE 10
11000-11	DURAVENT® SIZE 11
11000-12	DURAVENT® SIZE 12
11000-13	DURAVENT® SIZE 13
11001-05	DURAVENT® 1 IC, SIZE 5
11001-06	DURAVENT® 1 IC, SIZE 6
11001-07	DURAVENT® 1 IC, SIZE 7
11001-08	DURAVENT® 1 IC, SIZE 8
11001-09	DURAVENT® 1 IC, SIZE 9
11001-10	DURAVENT® 1 IC, SIZE 10
11001-11	DURAVENT® 1 IC, SIZE 11
11001-12	DURAVENT® 1 IC, SIZE 12
11001-13	DURAVENT® 1 IC, SIZE 13
11002-03	DURAVENT® 2 IC, SIZE 3
11002-04	DURAVENT® 2 IC, SIZE 4
11002-05	DURAVENT® 2 IC, SIZE 5
11002-06	DURAVENT® 2 IC, SIZE 6
11002-07	DURAVENT® 2 IC, SIZE 7
11002-08	DURAVENT® 2 IC, SIZE 8
11002-09	DURAVENT® 2 IC, SIZE 9
11002-10	DURAVENT® 2 IC, SIZE 10
11002-11	DURAVENT® 2 IC, SIZE 11
11002-12	DURAVENT® 2 IC, SIZE 12
11002-13	DURAVENT® 2 IC, SIZE 13

REF	Medical Device
11011-05	DURAVENT® UNI 1 ICU, SIZE 5
11011-06	DURAVENT® UNI 1 ICU, SIZE 6
11011-07	DURAVENT® UNI 1 ICU, SIZE 7
11011-08	DURAVENT® UNI 1 ICU, SIZE 8
11011-09	DURAVENT® UNI 1 ICU, SIZE 9
11011-10	DURAVENT® UNI 1 ICU, SIZE 10
11011-11	DURAVENT® UNI 1 ICU, SIZE 11
11011-12	DURAVENT® UNI 1 ICU, SIZE 12
11011-13	DURAVENT® UNI 1 ICU, SIZE 13
11072-05	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 5
11072-06	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 6
11072-07	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 7
11072-08	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 8
11072-09	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 9
11072-10	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 10
11072-11	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 11
11072-12	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 12
11072-13	DURAVENT® UNI-KOMBI LINGO 1 ICFU + 1 ICFK, SIZE 13
11081-05	DURAVENT® KOMBI 1 ICK, SIZE 5
11081-06	DURAVENT® KOMBI 1 ICK, SIZE 6
11081-07	DURAVENT® KOMBI 1 ICK, SIZE 7
11081-08	DURAVENT® KOMBI 1 ICK, SIZE 8
11081-09	DURAVENT® KOMBI 1 ICK, SIZE 9
11081-10	DURAVENT® KOMBI 1 ICK, SIZE 10
11081-11	DURAVENT® KOMBI 1 ICK, SIZE 11
11081-12	DURAVENT® KOMBI 1 ICK, SIZE 12
11081-13	DURAVENT® KOMBI 1 ICK, SIZE 13
11200-05	DURAVENT® XL SIZE 5
11200-06	DURAVENT® XL SIZE 6
11200-07	DURAVENT® XL SIZE 7
11200-08	DURAVENT® XL SIZE 8
11200-09	DURAVENT® XL SIZE 9

REF	Medical Device
11200-10	DURAVENT® XL SIZE 10
11200-11	DURAVENT® XL SIZE 11
11200-12	DURAVENT® XL SIZE 12
11200-13	DURAVENT® XL SIZE 13
11201-05	DURAVENT® XL 1 IC, SIZE 5
11201-06	DURAVENT® XL 1 IC, SIZE 6
11201-07	DURAVENT® XL 1 IC, SIZE 7
11201-08	DURAVENT® XL 1 IC, SIZE 8
11201-09	DURAVENT® XL 1 IC, SIZE 9
11201-10	DURAVENT® XL 1 IC, SIZE 10
11201-11	DURAVENT® XL 1 IC, SIZE 11
11201-12	DURAVENT® XL 1 IC, SIZE 12
11201-13	DURAVENT® XL 1 IC, SIZE 13
11211-05	DURAVENT® UNI XL 1 ICU, SIZE 5
11211-06	DURAVENT® UNI XL 1 ICU, SIZE 6
11211-07	DURAVENT® UNI XL 1 ICU, SIZE 7
11211-08	DURAVENT® UNI XL 1 ICU, SIZE 8
11211-09	DURAVENT® UNI XL 1 ICU, SIZE 9
11211-10	DURAVENT® UNI XL 1 ICU, SIZE 10
11211-11	DURAVENT® UNI XL 1 ICU, SIZE 11
11211-12	DURAVENT® UNI XL 1 ICU, SIZE 12
11211-13	DURAVENT® UNI XL 1 ICU, SIZE 13
11701-05	DURAVENT® IC XL SIZE 5
11701-06	DURAVENT® IC XL SIZE 6
11701-07	DURAVENT® IC XL SIZE 7
11701-08	DURAVENT® IC XL SIZE 8
11701-09	DURAVENT® IC XL SIZE 9
11701-10	DURAVENT® IC XL SIZE 10
11701-11	DURAVENT® IC XL SIZE 11
11701-12	DURAVENT® IC XL SIZE 12
11701-13	DURAVENT® IC XL SIZE 13
11708-05	DURAVENT® ICF PHON XL SIZE 5

REF	Medical Device
11708-06	DURAVENT® ICF PHON XL SIZE 6
11708-07	DURAVENT® ICF PHON XL SIZE 7
11708-08	DURAVENT® ICF PHON XL SIZE 8
11708-09	DURAVENT® ICF PHON XL SIZE 9
11708-10	DURAVENT® ICF PHON XL SIZE 10
11708-11	DURAVENT® ICF PHON XL SIZE 11
11708-12	DURAVENT® ICF PHON XL SIZE 12
11708-13	DURAVENT® ICF PHON XL SIZE 13
11711-05	DURAVENT® ICU XL SIZE 5
11711-06	DURAVENT® ICU XL SIZE 6
11711-07	DURAVENT® ICU XL SIZE 7
11711-08	DURAVENT® ICU XL SIZE 8
11711-09	DURAVENT® ICU XL SIZE 9
11711-10	DURAVENT® ICU XL SIZE 10
11711-11	DURAVENT® ICU XL SIZE 11
11711-12	DURAVENT® ICU XL SIZE 12
11711-13	DURAVENT® ICU XL SIZE 13
11785-05	DURAVENT® ICFK XL SIZE 5
11785-06	DURAVENT® ICFK XL SIZE 6
11785-07	DURAVENT® ICFK XL SIZE 7
11785-08	DURAVENT® ICFK XL SIZE 8
11785-09	DURAVENT® ICFK XL SIZE 9
11785-10	DURAVENT® ICFK XL SIZE 10
11785-11	DURAVENT® ICFK XL SIZE 11
11785-12	DURAVENT® ICFK XL SIZE 12
11785-13	DURAVENT® ICFK XL SIZE 13
11801-05	DURAVENT® IC SIZE 5
11801-06	DURAVENT® IC SIZE 6
11801-07	DURAVENT® IC SIZE 7
11801-08	DURAVENT® IC SIZE 8
11801-09	DURAVENT® IC SIZE 9
11801-10	DURAVENT® IC SIZE 10

REF	Medical Device
11801-11	DURAVENT® IC SIZE 11
11801-12	DURAVENT® IC SIZE 12
11801-13	DURAVENT® IC SIZE 13
11808-05	DURAVENT® ICF PHON SIZE 5
11808-06	DURAVENT® ICF PHON SIZE 6
11808-07	DURAVENT® ICF PHON SIZE 7
11808-08	DURAVENT® ICF PHON SIZE 8
11808-09	DURAVENT® ICF PHON SIZE 9
11808-10	DURAVENT® ICF PHON SIZE 10
11808-11	DURAVENT® ICF PHON SIZE 11
11808-12	DURAVENT® ICF PHON SIZE 12
11808-13	DURAVENT® ICF PHON SIZE 13
11811-05	DURAVENT® ICU SIZE 5
11811-06	DURAVENT® ICU SIZE 6
11811-07	DURAVENT® ICU SIZE 7
11811-08	DURAVENT® ICU SIZE 8
11811-09	DURAVENT® ICU SIZE 9
11811-10	DURAVENT® ICU SIZE 10
11811-11	DURAVENT® ICU SIZE 11
11811-12	DURAVENT® ICU SIZE 12
11811-13	DURAVENT® ICU SIZE 13
21032-05	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 5
21032-06	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 6
21032-07	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 7
21032-08	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 8
21032-09	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 9
21032-10	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 10
21032-11	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 11
21032-12	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 12
21032-13	DURAVENT® LINGO-PHON 1 IC + 1 ICF, SIZE 13
21042-03	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 3
21042-05	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 5

REF	Medical Device
21042-06	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 6
21042-07	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 7
21042-08	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 8
21042-09	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 9
21042-10	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 10
21042-11	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 11
21042-12	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 12
21042-13	DURAVENT® UNI LINGO-PHON 1 ICU + 1 ICF, SIZE 13
21072-05	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 5
21072-06	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 6
21072-07	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 7
21072-08	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 8
21072-09	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 9
21072-10	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 10
21072-11	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 11
21072-12	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 12
21072-13	DURAVENT® UNI-KOMBI LINGO-PHON 1ICU+1ICFK+1COMBIPHON®,SIZE 13
21073-05	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 5
21073-06	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 6
21073-07	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 7
21073-08	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 8
21073-09	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 9
21073-10	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 10
21073-11	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 11
21073-12	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 12
21073-13	DURAVENT® UNI-KOMBI LINGO-PHON 1IC+1ICU+1ICFK+1CP, SIZE 13
21242-05	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 5
21242-06	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 6
21242-07	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 7
21242-08	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 8
21242-09	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 9
21242-10	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 10

REF	Medical Device
21242-11	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 11
21242-12	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 12
21242-13	DURAVENT® UNI LINGO-PHON XL 1 ICU + 1 ICF, SIZE 13
21272-05	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 5
21272-06	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 6
21272-07	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 7
21272-08	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 8
21272-09	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 9
21272-10	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 10
21272-11	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 11
21272-12	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 12
21272-13	DURAVENT® UNI-KOMBI LINGO-PHON XL 1ICU+1ICFK+1CP,SIZE 13