

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	DURAPUR®
Basic UDI-DI	405194823000DURAPUR++TKHC
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
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Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
23000-07	DURAPUR® SIZE 7
23000-08	DURAPUR® SIZE 8
23000-09	DURAPUR® SIZE 9
23000-10	DURAPUR® SIZE 10
23000-11	DURAPUR® SIZE 11
23000-12	DURAPUR® SIZE 12
23001-07	DURAPUR® 1 IC SIZE 7
23001-08	DURAPUR® 1 IC SIZE 8
23001-09	DURAPUR® 1 IC SIZE 9
23001-10	DURAPUR® 1 IC SIZE 10
23001-11	DURAPUR® 1 IC SIZE 11
23001-12	DURAPUR® 1 IC SIZE 12
23011-07	DURAPUR® UNI 1 ICU SIZE 7
23011-08	DURAPUR® UNI 1 ICU SIZE 8
23011-09	DURAPUR® UNI 1 ICU SIZE 9
23011-10	DURAPUR® UNI 1 ICU SIZE 10
23011-11	DURAPUR® UNI 1 ICU SIZE 11
23011-12	DURAPUR® UNI 1 ICU SIZE 12
23032-07	DURAPUR® LINGO-PHON 1 ICF SIZE 7
23032-08	DURAPUR® LINGO-PHON 1 ICF SIZE 8
23032-09	DURAPUR® LINGO-PHON 1 ICF SIZE 9
23032-10	DURAPUR® LINGO-PHON 1 ICF SIZE 10
23032-11	DURAPUR® LINGO-PHON 1 ICF SIZE 11
23032-12	DURAPUR® LINGO-PHON 1 ICF SIZE 12
23081-07	DURAPUR® KOMBI 1 ICK SIZE 7
23081-08	DURAPUR® KOMBI 1 ICK SIZE 8
23081-09	DURAPUR® KOMBI 1 ICK SIZE 9
23081-10	DURAPUR® KOMBI 1 ICK SIZE 10
23081-11	DURAPUR® KOMBI 1 ICK SIZE 11
23081-12	DURAPUR® KOMBI 1 ICK SIZE 12
23200-08	DURAPUR® XL SIZE 8
23200-09	DURAPUR® XL SIZE 9
23200-10	DURAPUR® XL SIZE 10

REF	Medical Device
23201-08	DURAPUR® XL 1 IC SIZE 8
23201-09	DURAPUR® XL 1 IC SIZE 9
23201-10	DURAPUR® XL 1 IC SIZE 10
23211-08	DURAPUR® UNI XL 1 ICU SIZE 8
23211-09	DURAPUR® UNI XL 1 ICU SIZE 9
23211-10	DURAPUR® UNI XL 1 ICU SIZE 10
23232-08	DURAPUR® LINGO-PHON XL 1 ICF SIZE 8
23232-09	DURAPUR® LINGO-PHON XL 1 ICF SIZE 9
23232-10	DURAPUR® LINGO-PHON XL 1 ICF SIZE 10
23281-08	DURAPUR® KOMBI XL 1 ICK SIZE 8
23281-09	DURAPUR® KOMBI XL 1 ICK SIZE 9
23281-10	DURAPUR® KOMBI XL 1 ICK SIZE 10
23701-08	DURAPUR® IC XL SIZE 8
23701-09	DURAPUR® IC XL SIZE 9
23701-10	DURAPUR® IC XL SIZE 10
23801-07	DURAPUR® IC SIZE 7
23801-08	DURAPUR® IC SIZE 8
23801-09	DURAPUR® IC SIZE 9
23801-10	DURAPUR® IC SIZE 10
23801-11	DURAPUR® IC SIZE 11
23801-12	DURAPUR® IC SIZE 12
23807-07	DURAPUR® ICF SIZE 7
23807-08	DURAPUR® ICF SIZE 8
23807-09	DURAPUR® ICF SIZE 9
23807-10	DURAPUR® ICF SIZE 10
23807-11	DURAPUR® ICF SIZE 11
23807-12	DURAPUR® ICF SIZE 12
23808-07	DURAPUR® PHON ICF SIZE 7
23808-08	DURAPUR® PHON ICF SIZE 8
23808-09	DURAPUR® PHON ICF SIZE 9
23808-10	DURAPUR® PHON ICF SIZE 10
23808-11	DURAPUR® PHON ICF SIZE 11
23808-12	DURAPUR® PHON ICF SIZE 12
23809-07	DURAPUR® PHON ICF-O2 SIZE 7
23809-08	DURAPUR® PHON ICF-O2 SIZE 8

REF	Medical Device
23809-09	DURAPUR® PHON ICF-O2 SIZE 9
23809-10	DURAPUR® PHON ICF-O2 SIZE 10
23809-11	DURAPUR® PHON ICF-O2 SIZE 11
23809-12	DURAPUR® PHON ICF-O2 SIZE 12
23811-07	DURAPUR® ICU SIZE 7
23811-08	DURAPUR® ICU SIZE 8
23811-09	DURAPUR® ICU SIZE 9
23811-10	DURAPUR® ICU SIZE 10
23811-11	DURAPUR® ICU SIZE 11
23811-12	DURAPUR® ICU SIZE 12
23816-07	DURAPUR® ICFU SIZE 7
23816-08	DURAPUR® ICFU SIZE 8
23816-09	DURAPUR® ICFU SIZE 9
23816-10	DURAPUR® ICFU SIZE 10
23816-11	DURAPUR® ICFU SIZE 11
23816-12	DURAPUR® ICFU SIZE 12
23881-07	DURAPUR® ICK SIZE 7
23881-08	DURAPUR® ICK SIZE 8
23881-09	DURAPUR® ICK SIZE 9
23881-10	DURAPUR® ICK SIZE 10
23881-11	DURAPUR® ICK SIZE 11
23881-12	DURAPUR® ICK SIZE 12
23885-07	DURAPUR® ICFK SIZE 7
23885-08	DURAPUR® ICFK SIZE 8
23885-09	DURAPUR® ICFK SIZE 9
23885-10	DURAPUR® ICFK SIZE 10
23885-11	DURAPUR® ICFK SIZE 11
23885-12	DURAPUR® ICFK SIZE 12