
EG-Konformitätserklärung

EC Declaration of Conformity



DEHAS Medical Systems GmbH | Wesloer Str. 107-109 | 23568 Lübeck, Germany

**Produkt/
Medical device:**

Quality Flowmeter

**Artikelnummern/
Item numbers:**

Siehe Anhang
See attached list

**Klassifikation/
Classification:**

Ila

Satz 3.2, Regel 11, Anhang IX, Medizinprodukterichtlinie 93/42/EWG
Clause 3.2, Rule 11, Annex IX of Medical Device Directive 93/42/EEC

Wir erklären hiermit in alleiniger Verantwortung, dass das oben genannte Produkt mit den grundlegenden Anforderungen gemäß Anhang 1 der Medizinprodukterichtlinie 93/42/EWG übereinstimmt. Alle Belegdokumente werden in den Räumlichkeiten des Herstellers und der benannten Stelle aufbewahrt.

We hereby declare under our sole responsibility that the above product is in conformity with the basic requirements according to Annex 1 of the Medical Device Directive 93/42/EEC. All supporting documents are kept on the premises of the manufacturer and the notified authority.

**Konformitätsbewertungsverfahren/
Conformity assessment route:**

Anhang II (ohne Abschnitt 4) der Medizinprodukterichtlinie 93/42/EWG (Vollständiges Qualitätssicherungssystem)
Annex II (without section 4), Medical Device Directive 93/42/EEC (Full quality assurance system)

**Angewandte Normen/
Applied standards:**

EN 1041	EN ISO 10993-1	EN ISO 15001
EN ISO 14971	EN ISO 15223-1	EN ISO 15002
EN 62366-1	EN ISO 18562-1	EN ISO 780

Benannte Stelle/ Notified Body:

DNV Medcert GmbH, Pilatuspool 2, 20355 Hamburg, Germany

Kenn-Nummer/ ID number:

 0482

EG Zertifikats-Nr./ EC Certificate no.:

4153GB410200327

Ausstellungsdatum/ Date of issue:

2020-03-27

Ablaufdatum/ Expiry date:

2024-05-27

Lübeck, 2023/08/10



Jens Meincke

Regulatory Affairs Manager / Quality Manager

Anhang EG-Konformitätserklärung Attachment EC Declaration of Conformity

Produktliste / List of products

Artikelnummer / Product code	Produktbezeichnung/ Device name
D-B-FL-3	Quality Mix Flowmeter 0-3 l/min / Flow meter 0-3 LPM
D-B-FL-6	Quality Mix Flowmeter 0-6 l/min / Flow meter 0-6 LPM
D-B-FL-15	Quality Mix Flowmeter 0-15 l/min / Flow meter 0-15 LPM
D-B-FL-16	Quality Mix Flowmeter 0-16 l/min / Flow meter 0-16 LPM
D-B-FL-32	Quality Mix Flowmeter 3,2-32 l/min / Flow meter 3.2-32 LPM
D-B-FL-85	Quality Mix Flowmeter 8,5-85 l/min / Flow meter 8.5-85 LPM
D-BG-FL-1	Flowmeter BudgetMix 0-1 LPM
D-BG-FL-15	Flowmeter BudgetMix 0-15 LPM
D-B-FL-15-N2O	QualityMix Flowmeter 0-15 l/min O2/N2O / Flow meter 0-15 LPM O2/N2O
D-B-FL-15-NO	QualityMix Flowmeter 0-15 l/min O2/NO / Flow meter 0-15 LPM O2/NO
D-FA-OS-30	Flowmeter O2 0-30 LPM Anschluss 1/8", 180° / Flow meter 0-30 LPM connection 1/8", 180°
D-FA-OS-05	Flowmeter O2 0-3.5 LPM Anschluss 1/8", 180° / Flow meter 0-3.5 LPM connection 1/8", 180°
D-FA-OS-04	Flowmeter O2 0-15 LPM Anschluss 1/8", 180° / Flow meter 0-15 LPM connection 1/8", 180°
D-FA-OS-08	Flowmeter O2 0-1 LPM Anschluss 1/8", 180° / Flow meter 0-1 LPM connection 1/8", 180°
D-FL-O2-B-1	Cheap Flowmeter 0-1 LPM
D-FL-O2-B-8	Cheap Flowmeter 0-8 LPM
D-FL-O2-B-15	Cheap Flowmeter 0-15 LPM

NIST Anschluss vertikale Montage/ NIST connection vertical mounting:

Artikelnummer / Product code	Produktbezeichnung/ Device name
D-FL-O2-3-ST-NIST	QualityFlow Flowmeter direkt/ direct vertikale Montage/ vertical mounting 0-3l (O2)
D-FL-O2-6-ST-NIST	QualityFlow Flowmeter direkt/ direct vertikale Montage/ vertical mounting 0-6l (O2)
D-FL-O2-15-ST-NIST	QualityFlow Flowmeter direkt/ direct vertikale Montage/ vertical mounting 0-15l (O2)
D-FL-O2-16-ST-NIST	QualityFlow Flowmeter direkt/ direct vertikale Montage/ vertical mounting 0-16l (O2)
D-FL-O2-32-ST-NIST	QualityFlow Flowmeter direkt/ direct vertikale Montage/ vertical mounting 3.2-32l (O2)
D-FL-O2-85-ST-NIST	QualityFlow Flowmeter direkt/ direct vertikale Montage/ vertical mounting 8.5-85l (O2)

Direkt steckbar/ directly pluggable:

Artikelnummer / Product code	Produktbezeichnung/ Device name
D-FL-O2-3-DIN	QualityFlow Flowmeter direkt/ direct 0-3l (O2)

D-FL-O2-6-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 0-6l (O2)
D-FL-O2-15-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 0-15l (O2)
D-FL-O2-32-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 3.2-32l (O2)
D-FL-O2-85-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 8.5-85l (O2)
D-FL-AIR-3-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 0-3l (AIR)
D-FL-AIR-6-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 0-6l (AIR)
D-FL-AIR-15-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 0-15l (AIR)
D-FL-AIR-32-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 3.2-32l (AIR)
D-FL-AIR-85-DIN	QualityFlow Flowmeter direkt/ <i>direct</i> 8.5-85l (AIR)
D-FL-O2-3-BS	QualityFlow Flowmeter direkt/ <i>direct</i> 0-3l (O2)
D-FL-O2-6-BS	QualityFlow Flowmeter direkt/ <i>direct</i> 0-6l (O2)
D-FL-O2-15-BS	QualityFlow Flowmeter direkt/ <i>direct</i> 0-15l (O2)
D-FL-O2-32-BS	QualityFlow Flowmeter direkt/ <i>direct</i> 3.2-32l (O2)
D-FL-O2-85-BS	QualityFlow Flowmeter direkt/ <i>direct</i> 8.5-85l (O2)
D-FL-O2-3-NF	QualityFlow Flowmeter direkt/ <i>direct</i> 0-3l (O2)
D-FL-O2-6-NF	QualityFlow Flowmeter direkt/ <i>direct</i> 0-6l (O2)
D-FL-O2-15-NF	QualityFlow Flowmeter direkt/ <i>direct</i> 0-15l (O2)
D-FL-O2-32-NF	QualityFlow Flowmeter direkt/ <i>direct</i> 3.2-32l (O2)
D-FL-O2-85-NF	QualityFlow Flowmeter direkt/ <i>direct</i> 8.5-85l (O2)
D-FL-O2-3-SS	QualityFlow Flowmeter direkt/ <i>direct</i> 0-3l (O2)
D-FL-O2-6-SS	QualityFlow Flowmeter direkt/ <i>direct</i> 0-6l (O2)
D-FL-O2-15-SS	QualityFlow Flowmeter direkt/ <i>direct</i> 0-15l (O2)
D-FL-O2-32-SS	QualityFlow Flowmeter direkt/ <i>direct</i> 3.2-32l (O2)
D-FL-O2-85-SS	QualityFlow Flowmeter direkt/ <i>direct</i> 8.5-85l (O2)
D-FL-O2-3-CAR	QualityFlow Flowmeter direkt/ <i>direct</i> 0-3l (O2)
D-FL-O2-6-CAR	QualityFlow Flowmeter direkt/ <i>direct</i> 0-6l (O2)
D-FL-O2-15-CAR	QualityFlow Flowmeter direkt/ <i>direct</i> 0-15l (O2)
D-FL-O2-32-CAR	QualityFlow Flowmeter direkt/ <i>direct</i> 3.2-32l (O2)
D-FL-O2-85-CAR	QualityFlow Flowmeter direkt/ <i>direct</i> 8.5-85l (O2)
D-FL-O2-3-UNI	QualityFlow Flowmeter direkt/ <i>direct</i> 0-3l (O2)
D-FL-O2-6-UNI	QualityFlow Flowmeter direkt/ <i>direct</i> 0-6l (O2)
D-FL-O2-15-UNI	QualityFlow Flowmeter direkt/ <i>direct</i> 0-15l (O2)
D-FL-O2-32-UNI	QualityFlow Flowmeter direkt/ <i>direct</i> 3.2-32l (O2)
D-FL-O2-85-UNI	QualityFlow Flowmeter direkt/ <i>direct</i> 8.5-85l (O2)
D-A-FL15-DIN	Flowmeter O2 0-15 LPM, Anschluss DIN-Stecker, schwarzes Stellrad/ <i>connection DIN plug, black adjustment wheel</i>
D-A-FL15-DISS	Flowmeter O2 0-15 LPM, Anschluss DISS-Rändelmutter, grünes Stellrad/ <i>Connection DISS knurled nut, green adjustment wheel</i>

Schiene/ *rail*:

Artikelnummer / <i>Product code</i>	Produktbezeichnung/ <i>Device name</i>
D-FL-O2-3-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 0-3l (O2)
D-FL-O2-6-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 0-6l (O2)
D-FL-O2-15-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 0-15l (O2)
D-FL-O2-16-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 0-16l (O2)
D-FL-O2-32-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 3.2-32l (O2)
D-FL-O2-85-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 8.5-85l (O2)
D-FL-AIR-3-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 0-3l (AIR)
D-FL-AIR-6-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 0-6l (AIR)
D-FL-AIR-15-SH	QualityFlow Flowmeter Schiene/ <i>rail</i> 0-15l (AIR)

D-FL-AIR-32-SH	QualityFlow Flowmeter Schiene/ rail 3.2-32l (AIR)
D-FL-AIR-85-SH	QualityFlow Flowmeter Schiene/ rail 8.5-85l (AIR)
D-SFL-O2-85-SH	QualityFlow Stufenflowmeter O2 Schiene/ rail 8.5-85l (AIR)

Zubehör/ Accessories

Artikelnummer / Product code	Produktbezeichnung/ Device name
D-B-DK-9/16	Schalldämpfer/ Sound damper 9/16"
D-B-DK-22	Schalldämpfer/ Sound damper 22mm
D-EM019887	Adapter 9/16" auf 15/22 mm/ Adapter 9/16" to 15/22 mm
D-600122	Schlauchadapter Kunststoff, 9/16" auf 6 mm/ Hose adapter plastic, 9/16" to 6 mm

Ende der Liste / End of list