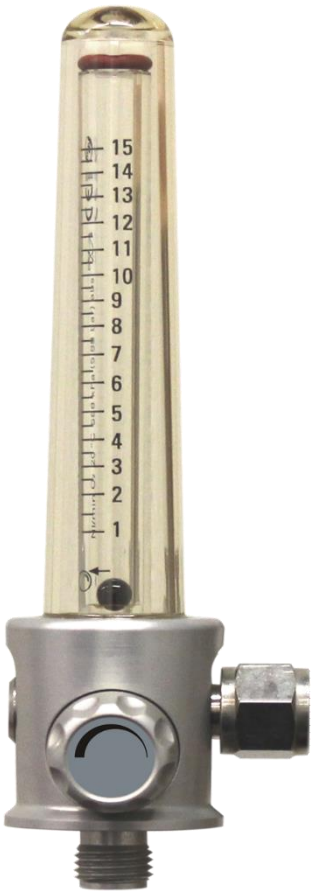
Operating Manual

Quality Flowmeter



Keep these instructions!

CE 0482

DEHAS Medical Systems GmbH
Wesloer Strasse 107-109
23568 Lübeck, Germany

Tel.: (+49) 451 80904-0
Fax: (+49) 451 80904-111
www.DEHAS.de

Version 1.9

Contents

Rev. 1.8 Version 27.01.2023

1. Foreword

This operating manual is intended to make it easier for the user to handle the device. Please keep this information safe and available.

2. Purpose

This flow meter is used to precisely control oxygen or air flow for medical purposes in the low pressure range (depending on the model).

This product is designed for use in home care applications, hospitals, other clinical environments and emergency services.

3. Safety information, warnings, precautions and identification information

Symbol	Description
CE 0482	This symbol indicates that the device complies with the regulation 93/42/EEC concerning medical devices and all applicable international standards.
WARNING	Indicates a potentially hazardous situation which, if not avoided, *could* result in death or serious injury.
CAUTION	CAUTION is used to indicate a potentially hazardous situation which, if not avoided, may result in property damage.
or	Refers the user to the necessity of consulting the operating instructions.
	DO NOT USE OIL
	Identifies the manufacturer of the medical device according to EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	Date of manufacture
UDI	Unique Device Identification
MD	Medical Device
NON STERILE	Unsterile

4. Before initial usage

Read all instructions before use!

This operating manual is intended to show trained professionals how to install and operate the device. It promotes safety and helps protect your device from damage. If you do not understand information or instructions in this document, do not use the device and contact your supplier.

WARNING

This product is not intended for use as a life-sustaining or life-supporting device.

WARNING

Read through the entire operating manual before you or others use this device, and before you show others how to use this flow meter. As with all medical devices, the usage of this device without a thorough understanding of its operation may result in injury to the patient or user.

- Medicated gases are, or should be, considered drugs. They should only be used for medical purposes as prescribed by a doctor or authorized clinician and only in accordance with their instructions.
- The flow meter may only be operated by trained medical personnel under the direct supervision of a licensed doctor.

The flow meter is not suitable for MRI usage!

- The flow meter may only be used for the purpose described in this operating manual.
- The flow meter may only be serviced by a qualified service technician.
- Ensure that the medical gas supply is adequate for the prescribed therapy and is within the pressure range specified in the device specification. If a gas cylinder is used for the supply, you should check the cylinder fill-level indicator regularly.
- This flow meter may only be used with the medical gas specified on the device label. Before usage, check that the gas cylinder or gas supply contains the correct medical gas. Always check that the flow meter is connected to the correct gas-specific supply connector.
- Gas-specific connectors are fitted to the flow meter. **Do not attempt to adapt these connections to other gases or fittings**.
- Always follow the EN and DIN standards for medical gas products, flow meters and the safe handling of oxygen.
- Do not remove the flow meter when it is under pressure.
- Securely attach the gas cylinder to a wall, stand or cart using the bracket provided,

in accordance with local safety regulations. Do not stand in front of a flow meter or regulator outlet when opening a gas cylinder valve.

- Do not allow liquid to enter this device.
- The accuracy of the flow meter can be significantly affected if the inlet pressure does not match the technical specification stated on the device label.
- Do not connect the flow meter output directly to another source of pressurized gas. This could damage one of the gas supplies (e.g., the connection of an O2 oxygen flow meter to an AIR flow meter via a Y-piece to mix their outputs).
- Use this flow meter only when the flow tube is in its intended vertical position. Otherwise, incorrect flow rates may be displayed or the device may stop functioning.
- Make sure that the flow control valve is not clogged or blocked. Make sure there is no unwanted pressure. In such cases, temporary changes in the gas flow may occur.
- Arrange the gas supply hoses carefully to avoid damaging them and to avoid a tripping hazard. Never pull or apply excessive force to the gas hoses. This could damage them. A leaking hose can cause high local concentrations of oxygen or other gases, which presents a fire hazard.

Oxygen itself is not combustible. However, the presence of an enriched concentration of oxygen in the environment dramatically increases the rate and severity of combustion. Oil and/or grease in the presence of an oxygen-enriched atmosphere become highly flammable. Thus, oxygen must never be exposed to oil, grease or other petroleum-based substances.

This device must be kept free of oil and grease!

- Do not smoke near oxygen devices
- NOT suitable for sterilization or autoclaving
- Do NOT use if contamination is present
- Do NOT clean with aromatic hydrocarbons

CAUTION:

The performance of the flow meter may be affected if it is stored or transported at temperatures outside the range of -20 °C to +50 °C.

The flow meter's performance may be affected if the flow control valve is tightened too tightly when the flow is shut off. Apply only the minimum force necessary to shut off the gas flow.

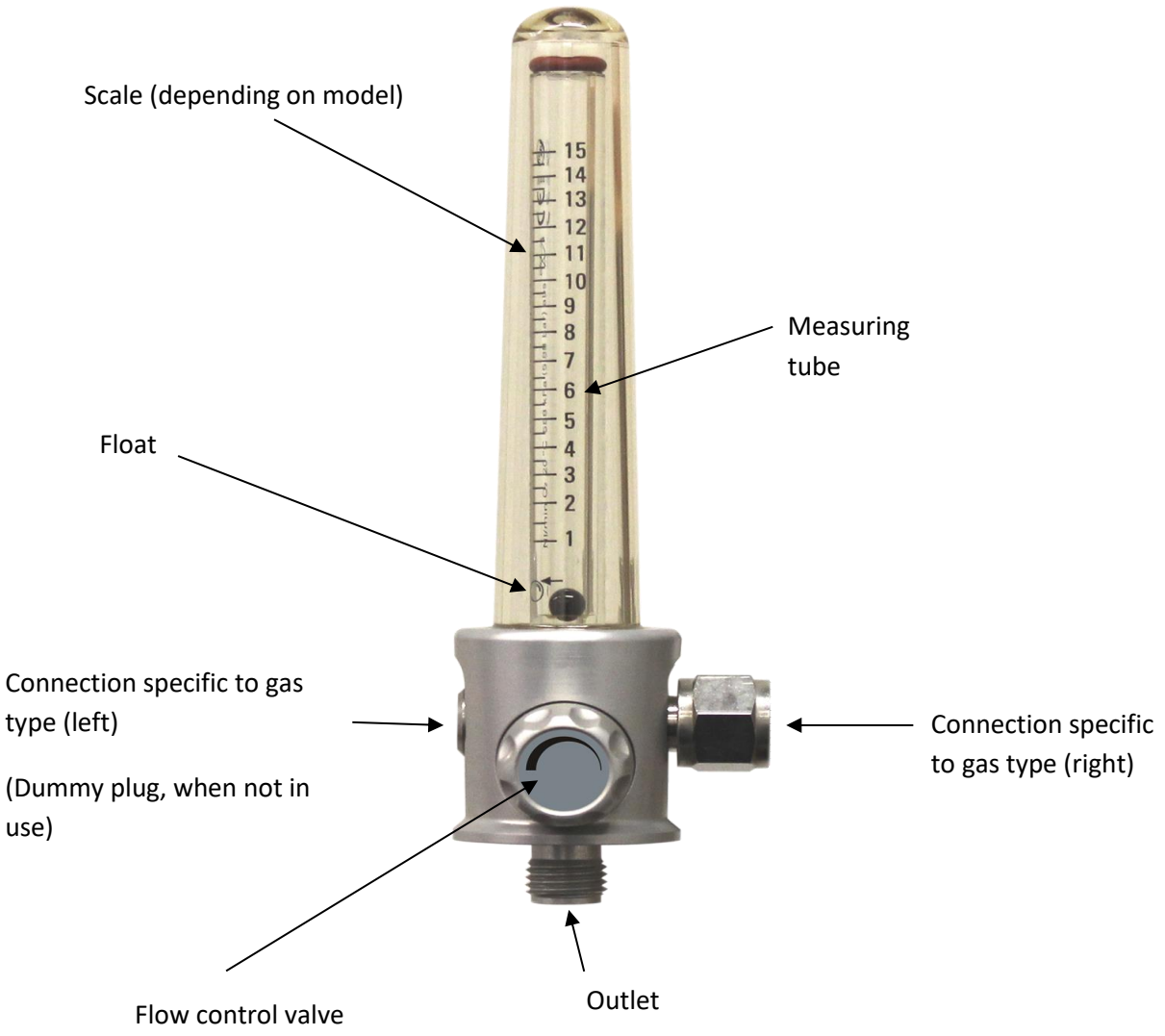
5. Performance data

Construction type:	Pressure-compensated flow meter for medical gases. Display uses the float principle.
Material:	Main body: aluminium / stainless steel Flow tube: polycarbonate (PC)
Accuracy:	Nominal (rated) pressure: ±10% or 0.5 l/min (whichever is greater) of the displayed measured value Temperature: 3% increase or decrease in flow rate per 5 °C increase or decrease in temperature Inlet pressure: 4% increase/decrease per 10 kPa increase/decrease in pressure compared to nominal pressure
Inlet pressure range / supply pressure range:	450 kPa ± 50 kPa
Medical gases:	O2, AIR, O2/AIR O2/NO, O2/N2O
Inlet:	G1/4", DIN, NF, AGA, BS, Uni probe, NIST
Outlet:	9/16"-18 UNF, hose nipple, external thread G1/4", G 3/8", 9/16" UNF
Performance: Scaling:	Depending on the model: 0 – 3 l/min 0 – 6 l/min 0 – 15 l/min 0 – 32 l/min 0 – 85 l/min
Environmental influences:	Transport and storage temperature: -20 °C to +50 °C Operating temperature 0 °C to +50 °C Humidity: 0 – 95% RH non-condensing
Standards:	ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems ISO 15001 Anaesthetic and respiratory equipment, Compatibility with oxygen ISO 5359 Low pressure hose assemblies for use with medical gases

	EN ISO 14971 Medical devices, Application of risk management to medical devices EN ISO 15223-1 Medical devices, Symbols to be used with medical device labels, labelling and information to be supplied General requirements

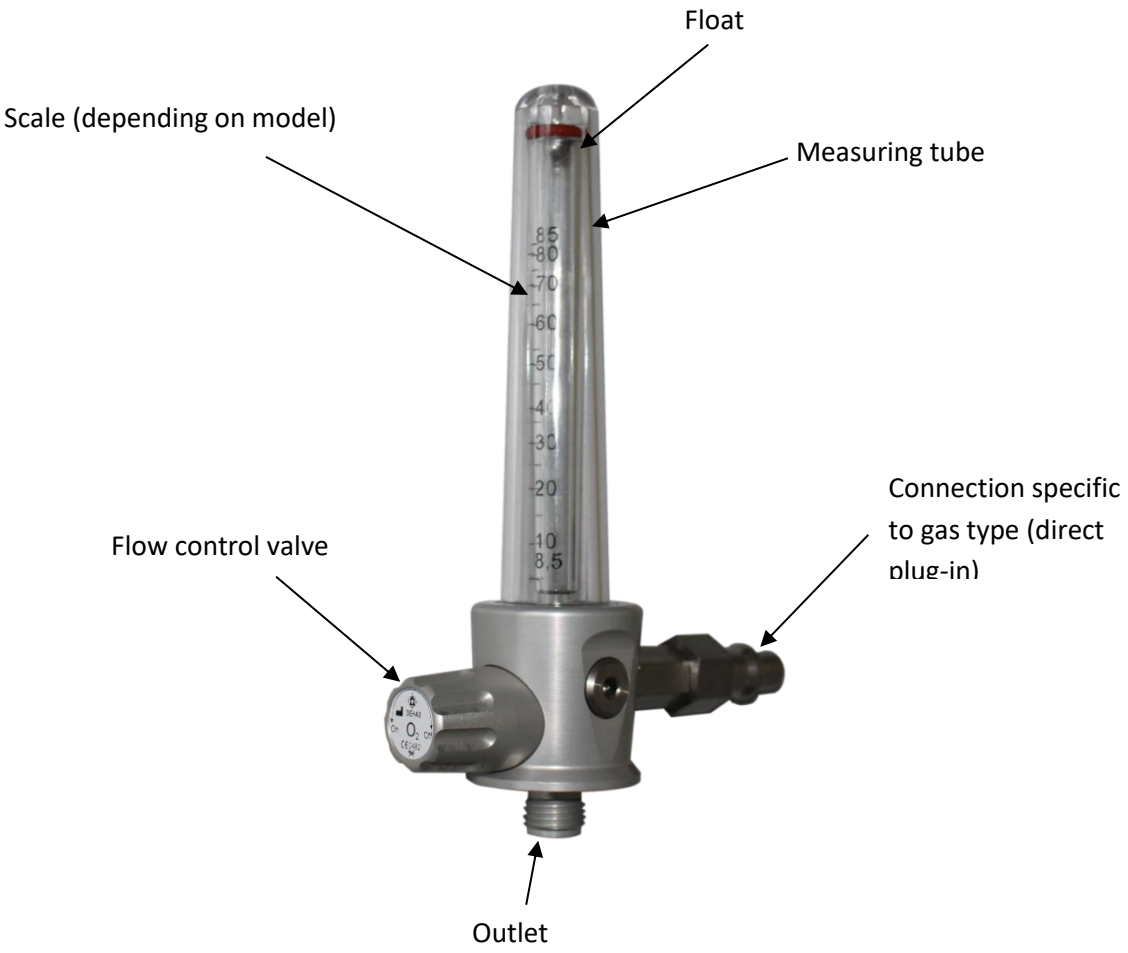
6. Functional description

a) Standard version



This figure shows the standard version of the Quality Flowmeter

b) Direct plug-in version



This figure shows the direct plug-in version of the Quality Flowmeter (specific connectors DIN; NF; BS; SS; AGA: CH, Carbamed; UNI)

7. General technical description

The flow meter enables the precise control of oxygen or air flow for medical purposes in the range of 0 to 85 l/min (depending on the model). A precision-manufactured rotating sphere rises in a transparent measuring tube. A scale is printed on the measuring tube, on which the speed of the gas flow is displayed in litres per minute (l/min). The gas flowing through the measuring tube is controlled by a downstream valve.

This flow meter was designed for connecting to an air-oxygen mixer (for example). However, it can also be operated as a "stand-alone" device for connecting directly to the medical gas supply.

Connections for specific gas types

The gas-specific quick connectors that are used have features to prevent them being used with the wrong type of gas.

Connecting to the patient

Connect the other end of the oxygen tubing to the patient or environment (device) using the appropriate connector.

Adjusting the gas flow

The flow control valve (knob) must be turned counter-clockwise to turn it on and increase the gas flow. Do not use the flow meter if it is not functioning properly. Refer to Section 11 of this manual for troubleshooting instructions.

During use

During therapy or treatment, continuously monitor the gas flow and the fill level of the gas cylinder (when in use). Also, ensure that the supply is secured and that the supply hose (when in use) cannot pose a tripping hazard.

After use

If a gas cylinder is being used for the supply, the cylinder valve must be closed after the treatment or therapy is finished and the flow meter must be removed.

8. Operating

WARNING
Safety instructions to prevent accidents during the use of an oxygen handling device: **The user is responsible for avoiding any enrichment of the room air or ambient air with a volume fraction > 21% O2.**

Connecting the gas supply

Before use, visually inspect the flow meter and hose (when being used) for damage or contamination. Do not connect or use the device if there is any doubt about its operating condition.

The flow meter is delivered with a gas-specific connector designed for connecting to a suitable gas-specific outlet. A gas-specific outlet may be an end unit (withdrawal port) in a medical gas piping system or part of a pressure regulator outlet on a gas cylinder.

If you are using a gas cylinder as the supply source, ensure that the contents of the gas cylinder are sufficient for the planned therapy or treatment and switch on the supply at the gas cylinder.

Connect the gas-specific quick connector to the appropriate gas-specific outlet.

Align the flow meter to the intended vertical position. Fully tighten the connection by hand before turning on the supply pressure.

For quick-connect fittings (e.g. BS, DIN, NF, SS, AGA, CH, UNI), ensure that the connection has been correctly established by gently pulling on the housing of the flow meter or hose (if applicable) before turning on the supply pressure.

Setting the flow

Turn the flow control valve (knob) counter-clockwise to turn on and increase the gas flow.

If the flow meter does not operate properly, remove it from service. Then, refer to the troubleshooting guide in Section 11 of this manual.

Reading the flow meter correctly:

The set flow rate can be read from the mark on the floating ball scale (at the top of the floating ball).

Connecting to the patient:

Connect the other end of the oxygen tubing to the patient or environment (device) using the appropriate connector.

During use

During therapy or treatment, continuously monitor the gas flow and the fill level of the gas cylinder (when in use). Also, ensure that the supply is secured and that the supply hose (when in use) cannot pose a tripping hazard.

After use

If a gas cylinder is being used for the supply, the cylinder valve must be closed after the treatment or therapy is finished and the flow meter must be removed.

9. Cleaning / disinfection

Make sure that the flow meter is disconnected from the gas supply before cleaning it!

 **CAUTION**
• **NOT suitable for sterilization or autoclaving.** • **Do not disassemble the flow meter.** • **NEVER immerse the device in liquids.** • **Do NOT use strong solvents or abrasives.** • **Do NOT clean with aromatic hydrocarbons.**

The outside of the device must be disinfected at regular intervals or at least after each use on the patient, in accordance with the applicable hygiene standard.

If you suspect that the flow meter is contaminated, remove it from service and report the contaminated device to the appropriate department.

Never immerse the flow meter in liquid or attempt to clean internal parts.

Cleaning and disinfection steps:

Manufacturer:	Sterilization procedure:	
DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Lübeck, Germany	N/A This product is not intended for the sterilization process.	

Described product:

Quality Flowmeter

WARNINGS	Do not use disinfectants containing phenol. Do not use strong solvents or abrasive cleaners. Do not clean with aromatic hydrocarbons. Do not autoclave! Do not sterilize! Do not immerse in liquids!
The instructions listed have been validated as SUITABLE by the medical device manufacturer for preparing a medical device for reuse. The reprocessor is responsible for ensuring that the actual reprocessing performed with the equipment, materials, and personnel used in the reprocessing facility achieves the desired results.	

INSTRUCTIONS	
Preparation for decontamination:	The outside of the unit must be wiped clean at regular intervals or at the latest after each patient in accordance with the applicable hygiene standards.
Cleaning: Manual	For this procedure: 1. Disconnect all gas connections from the unit before cleaning. 2. Wipe the outside of the flow meter with a cloth soaked in alcohol. 3. Wipe dry with a dry cloth.
Disinfection: **Manual**	1. Disconnect all gas connections from the unit before disinfection. 2. Wipe the outside of the flow meter with a cloth soaked in disinfectant.

	3. Observe the disinfectant manufacturer's exposure time according to the required spectrum of activity. 4. after the exposure time specified by the disinfectant manufacturer, wipe the device with a dry cloth.
Manufacturer's recommendation:	The manufacturer recommends the use of the disinfectant Bacillol ® 30 Foam, Bacillol ® 30 Tissues, Bode Chemie GmbH & Co. The current product data sheet of the disinfectant manufacturer must be observed.

10. Maintenance

Inspection / checks

The flow meter should be regularly cleaned, checked for damage, and inspected for proper performance. The frequency of inspections and performance checks depends on the actual usage. If the flow meter is used daily, this may need to be carried out every six months. In the case of infrequent usage, an annual inspection may be sufficient.

Leakage test

Connect the flow meter to a low-pressure medical gas supply with the rated supply pressure (as specified on the device's ratings plate) and close the flow control valve. Connect the supply hose to the outlet of the flow meter and immerse the other end of the supply hose in water. A leak is indicated by the presence of gas bubbles in the water. A flow meter that does not pass these tests should no longer be used.

Flow test

Check the flow rates at all flow settings against the specifications (i.e. within ± 10% or 0.5 l/min (whichever is higher) at 1 l/min and above).

Service and repair

Maintenance measures and inspections are carried out depending on the type of use, the conditions of use and the intensity of use. The intervals must be defined by the user. However, the flow meter should be cleaned regularly, checked for signs of damage and checked for proper performance. In addition, all silicone seals used in the device must be checked regularly for proper condition and correct function. They should be replaced as necessary. An interval of 2 years is recommended.
For flow meters with indirect connections, the hose should be replaced according to the replacement date specified by the manufacturer. The date of manufacture can be found on the device label of the hose.

11. Troubleshooting

Error	Possible cause	Problem resolution
No gas flow	Flow meter is not connected properly	Check the gas supply. Check that the gas-specific connection is properly connected.
	Gas cylinder is empty	Replace the gas cylinder
	The medical gas terminating unit of the gas piping system is not connected or active.	Seek advice from someone authorized to operate the medical gas piping system and its shut-off valves.
	The inlet filter is blocked	Repair is necessary
Audible leakage	Seal is worn or damaged	Carry out a leakage test with leak detection spray. Repair may be necessary; sealing ring must be replaced.
	Pressure relief valve is leaking because the inlet pressure is too high	Check that the pressure of the gas supply is within the specified range for the device.
	Cover tube is cracked or damaged	Repair is necessary Cover tube must be replaced.
	Connection worn or damaged.	Repair is necessary; replace the connection
	Gas supply hose is damaged	Replacement is necessary. Replace the connecting hose.
There is a gas flow although the regulator valve is closed	Regulator valve or valve seat is damaged	Repair is necessary
The measured set flow rate is outside the tolerance range	Cover tube of the flow meter is not screwed on properly.	Inform a trained specialist from the medical technology department. Carry out a leakage test with leak detection spray. Check whether the cover tube is firmly screwed onto the base housing.
	O-ring in the base housing dome has slipped.	Inform a trained specialist from the medical technology department. Carry out a leakage test with leak detection spray. Check that the O-ring in the main housing dome is sealed properly.

12. Articles and spare parts

Article:

Article number	Description / Version / Performance
D-B-FL-3	Quality Flowmeter 0 – 3 l/min
D-B-FL-6	Quality Flowmeter 0 – 6 l/min
D-B-FL-15	Quality Flowmeter 0 – 15 l/min
D-B-FL-16	Quality Flowmeter 0 – 16 l/min
D-B-FL32	Quality Flowmeter 0 – 32 l/min
D-B-FL-85	Quality Flowmeter 0 – 85 l/min

Spare parts:

Part number	Description
D-EM019681	Dummy plug for base housing
D-EM016583	Adapter 9/16"
D-EM028496	O-ring for base housing
D–0232900	Cover tube

13. Customer service / warranty

a. Warranty

The warranty period for this device is 12 months, starting from the date of sale, in accordance with the following conditions:

If, within the applicable period, a device defect should occur, then the dealer shall – after written notification thereof and substantiation that the device has been stored, installed, maintained and operated in accordance with the instructions of the dealer and in accordance with standard industry practice, and that no modifications, substitutions or changes were made to the product – correct such a defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE A WARRANTY.

The dealer is not authorised to make oral warranties about the merchandise described in this contract. Any such statements are not binding and not part of the sales contract. Thus, this written second statement is a final, complete and exclusive statement of the contractual terms.

– Subject to technical changes!

b. Returning the device

Please contact your retailer. They will help to coordinate the return. It is important that you provide a description of the error or malfunction so that the return can be processed effectively. All returns must be shipped in sealed containers to prevent damage. The specialist retailer is not responsible for any devices that are damaged during transport.

c. Disposal

This device and its packaging contain no hazardous materials. No special precautions are required when disposing of the device and its packaging.

Please clean and disinfect before disposal, and then recycle.

14. Declaration of Conformity

DECLARATION OF CONFORMITY

DEHAS Medical Systems GmbH
Wesloer Strasse 107-109
23568 Lübeck, Germany
GERMANY

CE 0482

Quality Mix Flowmeter (all variants)

Classification:	IIa
Classification criteria:	Clause 3.2, Rule 11 of Annex IX of the MDD

We hereby declare with sole responsibility that the above products comply with the following guidelines and standards of the EC Council. All supporting documents are kept on the premises of the manufacturer and the notified authority.

Directives:	General Application Guidelines: Medical Device Directive (MDD), Council Directive 93/42/EEC of 14 June 1993 Annex II, 3 on medical devices of the European Parliament.	
Applied standards:	EN 1041	ISO 18562-1
	EN ISO 14971	ISO 18562-2
	EN ISO 15001	ISO 18562-3
	EN ISO 15002	ISO 10993-1

Notified authority:	DNV Medcert GmbH / CE 0482
Address:	Pilatuspool 2, 20355 Hamburg, GERMANY
Certificate number:	4153DE410200327 Expiration date: 05/2024
Devices already manufactured:	Traceable by serial number
Valid from/to:	27-03-2020 until expiration date
Manufacturer representative:	Quality manager
Position:	Quality systems
Date of issue:	03-04-2020

15. Manufacturer information

Manufacturer	DEHAS Medical Systems GmbH Wesloer Strasse 107-109 23568 Lübeck, Germany Germany Phone: +49 451 80 90 4 - 112 Fax: +49 451 80 90 4 - 111 E-mail: Info@dehas.de Homepage: www.dehas.de	CE 0482

Sales and distribution	DEHAS Medical Systems GmbH Wesloer Strasse 107-109 23568 Lübeck, Germany Germany Phone: +49 451 80 90 4 - 112 Fax: +49 451 80 90 4 - 111 E-mail: Info@dehas.de Homepage: www.dehas.de

Rev. 1.9 Version 17.08.2023