Operating Instructions

The Quality MonO2

Oxygen Monitor

Save these instructions!

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0482

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1. Contents of delivery; Inspection upon receipt

Contents of the delivery:	1	Quality MonO2 oxygen monitor	D-B-QMon-O2
	1	Sensor cable	D-B-QMon-Cable
	1	ENVITEC OOM111 O2 sensor	01-00-0114
	1	Flow diverter	1-002171
	1	Tee piece	46-006005 (optional)
	1	Blender Buddy	D-B-B-O2 (optional)
	1	Operating instructions	

Inspection: Take the device out of its packaging and inspect it for damages. Do NOT use the device if you detect any damage. Contact your supplier.

2. Intended usage

The Quality MonO2 oxygen monitor is used to monitor oxygen levels in respiratory gas mixtures for medical applications. The Quality MonO2 can be used for monitoring the respiratory gas mixture of anaesthesia and ventilation equipment, as well as for monitoring infant incubation.

The Quality MonO2 can also be used for mobile use because of its compact design, light weight and user-friendly controls.

Indication: The oxygen content of respiratory gas needs to be monitored.

Contraindications: Not suitable for personal protection. Do not use for monitoring the production of gaseous mixtures.

3. Before initial usage

Read all instructions before use!

These operating instructions are intended to show trained professionals how to install and operate the Quality MonO2. They promote safety and protect your device from damage. If you do not understand information or instructions in this document, do not use this device and contact your supplier.

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

4. Explanation of the key abbreviations

l/min	litre per minute
TRHS	Technical Rules for Hazardous Substances
O_2	Chemical formula for oxygen
N_2	Chemical formula for nitrogen
CO_2	Chemical formula for carbon dioxide
N_2O	Chemical formula for nitrous oxide

5. Safety information – warnings and cautions

General information

These Operating Instructions are considered a part of the device. This document should always be kept near the device. If inconsistencies or problems occur during your usage that cannot be clarified by these instructions, please contact us for clarification. We will check whether a change in the Operating Instructions is necessary.

Strict adherence to the instructions is required to operate the device as intended. You must also follow these instructions in order to ensure the necessary level of safety.

There are no warranty claims for damage caused by use of inappropriate accessories and consumables.

Explanation of symbols

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.

REFER TO THE ACCOMPANYING DOCUMENTS

This symbol indicates that the device complies with the regulation 93/42/EEC concerning medical devices and all applicable international standards.

Defective devices and empty batteries should not be put in household waste. They must be disposed of in accordance with the relevant national or regional regulations.

Safety notices

 **WARNING**
This device is not approved for operation in hazardous explosive-risk areas. **The device must not be used for the purpose of personal protection and for the production of gas mixtures.**

With regard to the oxygen sensor used in the device, the following safety notices from the manufacturer must be observed:

 **WARNING**
Do not mechanically damage the sensor. Do not use damaged products. Do not use for other purposes. <u>Possible dangers</u> Dangers for humans and the environment: Lead and lead compounds: Harmful if swallowed, inhaled (as dust) or absorbed via the skin; use protective measures in accordance with TRHS 505 (6/88). Potassium hydroxide solution: in compliance with GefStoffV (German Regulation on Hazardous Materials), classified as "corrosive": acid burns result from skin and eye contact. Do not disinfect with liquid. Remove dirt or impurities with a damp disposable cloth. <u>Notices concerning the disposal of the oxygen sensor product</u> Recommendation: Dispose of in accordance with regulations by incinerating at a hazardous waste incineration facility. Follow all applicable regional regulations. Do not dispose of in household garbage. EAK key 160202 and 160606 <u>Regulations</u> Marked in accordance with GefStoffV as "corrosive" for the KOH solution component

6. Technical specifications

Technical specifications are subject to change without notice.

All technical specifications apply to the standard conditions:

An ambient pressure of 1013 hPa and dry ambient air at 25 °C

Characteristic	Specification
Measuring range	0-100% oxygen
Display accuracy	0.1% oxygen
Accuracy	< 1% vol. O_2, when calibration is carried out on 100% O_2
Offset	<1% vol. O_2 in 100% N_2
Response time	< 12 sec. at 90% of the final value
Linearity error	< 3% relative
Drift	< 1% vol. O_2 over 8 hours
Cross-sensitivity (quench)	< 0.1% vol. O_2 in reaction to: 10 % CO_2 Rest N_2 80% N_2O Rest N_2 7.5% halothane residual N_2 7.5% isoflurane residual N_2 7.5% enflurane residual N_2 9% sevoflurane residual N_2 20% desplurane residual N_2
Influence of moisture	0.03% relative per RH
Pressure effect	Proportional to the change in partial oxygen pressure
Shock sensitivity	<1% relative to a fall from 1 m height
Operating temperature	0-0 °C
Temperature compensation	Built-in NTC compensation
Operating humidity	0-99% rel. humidity
Storage temperature	-20 to 50 °C
Recommended storage	5 to 15°C
Battery type	Three AAA batteries / 4.5V
Protection degree	IP 40

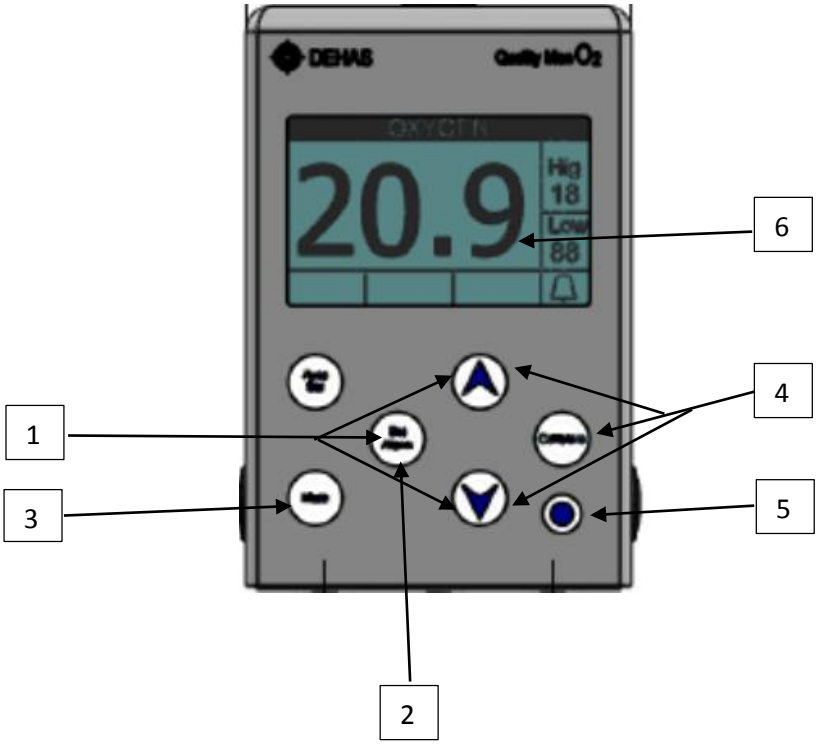
7. Electromagnetic compatibility

	Guidelines and manufacturer's declaration for electromagnetic emissions		
2	The Quality MonO2 is intended for use in the conditions described below. The customer or user of the Quality MonO2 should ensure that it is always operated in a compliant environment.		
3	Emissions	Accordance	Electromagnetic Environment - Guidance
4	HF emissions CISPR 11	Group 1	The Quality MonO2 uses high-frequency energy only for its internal function. Therefore, its high frequency (HF) emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
6	HF emissions CISPR 11	Class B	
7	Harmonic frequency emissions IEC 61000-3-2	Not applicable	
8	Emission of voltage fluctuations IEC 61000-3-3	Not applicable	
9			The Quality MonO2 can be used in any building (including living areas) where there is a direct connection to a public power supply network that supplies residential buildings.

Guidelines and manufacturer's declaration for electromagnetic emissions			
The Quality MonO2 is intended for use in the conditions described below. The customer or user of the Quality MonO2 should ensure that it is always operated in a compliant environment.			
Inspecting the interference immunity	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV Air discharge	± 6 kV ± 8 kV	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, then the relative humidity must be at least 30%.
Power supply frequency (50/60) Hz IEC 61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields should correspond to the typical values for hospital and business environments.
Conducted HF interference variables IEC 61000-4-6	3 V 150 kHz – 80 MHz	3 V	Portable and mobile radio devices must not be used too near the Quality MonO2 (and its cables). Maintain the recommended safety clearances: d > 0.3m
Radiated HF interference variables IEC 61000-4-3	3 V/m 80 MHz – 800 MHz	3 V/m	d > 0.1 m
Radiated HF interference variables IEC 61000-4-3	3 V/m 800 MHz – 2.5 GHz	3 V/m	d > 0.2m

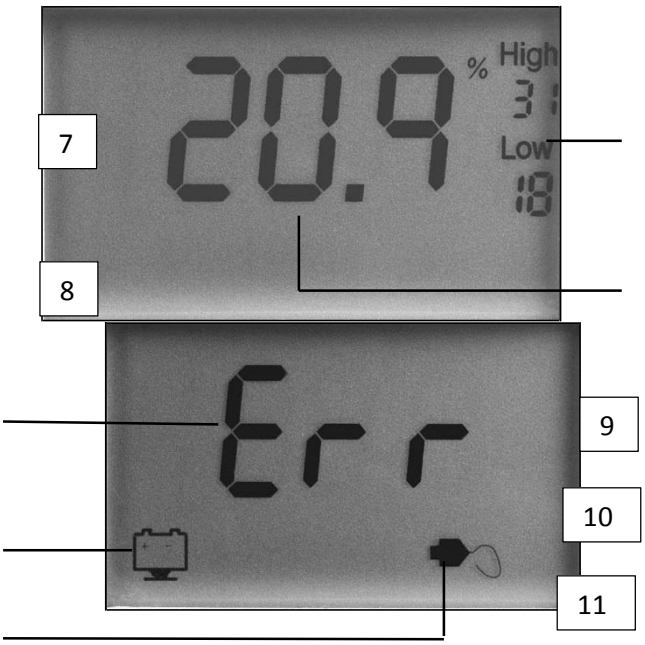
8. Illustrations and identification of components

CAUTION
If you follow the instructions regarding the sterilization, the labelling on the device should remain readable. Contact DEHAS or your local representative if the labelling becomes unreadable.



Position	Description
1	Alarm buttons (alarm limits) with LED for visual alerts. Press (and hold for about 3 seconds) the "ALARM" button; then press "▲ " or "▼ " to change the alarm limit. -> *See* also *Chapter 11 Setting the alarm*
2	Alarm button (alarm auto set) Press (and hold for about 3 seconds) the "AUTO SET" button to reset the alarm limits to their default values. -> *See* also *Chapter 11 Setting the alarm*
3	Alarm button (silence) Press the "Mute" button to suppress the audible alarm for about 1 minute. -> *See* also Chapter *11 Setting the alarm*
4	Calibration button Press (and hold for about 3 seconds) the "CAL" button. Then press "▼" to calibrate at 21% or "▲" to calibrate at 100% (so that the device is calibrated with normal air or with 100% oxygen) -> *See chapter 10 Calibration and measurement accuracy*
5	ON/OFF button Press the ON/OFF button and hold for 2 seconds to switch on the Quality MonO2. Also press this button and hold for 2 seconds to switch the device off.
6	LCD (display) The display shows the oxygen concentration in the range from 0 – 100% O_2.

The display



Position	Description
7	Upper and lower alarm limits
8	Oxygen concentration in vol. % O2
9	Device error
10	Battery indicator
11	Sensor error

When the battery indicator is displayed constantly, the batteries should be replaced because they can only provide the required voltage for a short time more. The batteries are nearly empty when this display is flashing. If the battery indicator flashes briefly when you turn on the device and then goes out immediately, this indicates that the batteries are empty and the device cannot be used. The batteries must be replaced.

Symbols on the Quality MonO2

There are several symbols on the device that provide guidance on safe usage

Symbol	Description
	Follow the operating instructions!
	The device is type BF; it is not protected against the effects of defibrillators.
	Date of manufacture

9. Commissioning

1. <u>Connecting the oxygen sensor</u>

Using the tee piece	Using the Blender Buddy
	

Both figures show the same sensor cable. The colour differences are caused by the lighting.

The sensor cable is connected to the port (1) on the back of the monitor that is connected to the device.
The flow diverter is screwed onto the sensor (3).
The sensor (3) is connected to the sensor cable via the sensor receptacle (2).

Note: Make sure that you push the sensor all the way into the receptacle until it can go no further.

2. Switching on the monitor

Press and hold the ON/OFF button (for more than 2 seconds) to switch on the monitor. It then carries out a self-test. A measured value will be displayed when the sensor is properly connected to the device.

➔ The measured value is displayed:
The Quality MonO2 is functioning properly.

➔ No measured value is displayed or there is an error message:
The Quality MonO2 is not functioning properly; see Chapter 10, section 3 for troubleshooting information.

3. Calibrating the Quality MonO2

Refer to Chapter 10 Calibration and measurement accuracy

4. The device is ready to take measurements after the calibration has finished successfully.

5. Connecting to the gas-bearing system

Place the sensor with the flow diverter (depending on your selected version) in the tee (4) or the Blender Buddy.

10. Calibration and measurement accuracy

1. Calibrating with the ambient air

- Switch on the Quality MonO2.
- Hold the sensor away from your body.
- Press the calibration button "Calibrate" ("CAL" flashes). Then press "" ("20,9%" flashes) and press then the calibration button once again. The device automatically calibrates with the ambient air.
- The display alternates between "CAL" and "21" for about 5 seconds.
- The device is ready to take a measurement.

Note: The oxygen concentration of the ambient air is 20.95% O_2. This results in a calibration value of 20.9% O_2. The atmospheric pressure, humidity and temperature influence the displayed value *(refer to section 4).*

2. Calibrating with 100% oxygen

Note: When measuring high concentrations of oxygen (50 – 100%), we recommend using a calibration gas of 100% oxygen. Make sure that the connection between the oxygen sensor and the receptacle does not leak when gas is reaching the sensor. It must not be possible for ambient air to mix in with the oxygen; this would falsify the calibration.

- Connect the tee with the oxygen supply. Insert the sensor and flow diverter into the tee as well.
- Adjust the oxygen flow. We recommend using a flow of 2 l/min and gassing the sensor at least 1 minute prior to the calibration.
- Press the calibration button "Calibrate" ("CAL" flashes on the display). Then press "  " ("100%" flashes) and then press the calibration button once again. The device automatically calibrates with the pure oxygen.
- The display alternates between "CAL" and "100" for about 5 seconds.
- Remove the sensor from the receptacle. Now check for one minute if a reading of 21% O_2 results from a test measurement in ambient air.
- Hold the sensor away from your body and swivel it. No breathing exhalations should reach the sensor! If necessary, unscrew the flow diverter.
- The device is ready to take a measurement.

CAUTION

The respective calibration should be checked prior to each new measurement or repeated! If the calibration cannot be performed correctly, refer to the section 3 (*Errors in calibration and measurement recording*) in this chapter or contact your dealer.

3. Errors in calibrating and recording measured values

Fault or error	Possible cause
The measured value fluctuates by more than 1 vol. % of O_2.	➢ The sensor should be the same temperature (in thermal equilibrium) as the environment. ➢ Avoid thermal transfer from hands to the sensor. ➢ Observe the sensor's adjustment time (refer to the label). ➢ The sensor's opening must be clean and dry. ➢ Gas has mixed with ambient air during calibration. ➢ Internal electrical fault in the device → Contact your dealer!
The device does not display the expected measured value.	➢ The calculation of the gas mixture is incorrect. ➢ The pressure gauge is defective. ➢ The device is not calibrated. ➢ The sensor is not in thermal equilibrium with the ambient surroundings. ➢ Ambient gases have mixed in.
After being switched on, the device displays "ERR".	➢ Send in the device to the dealer or manufacturer for inspection!
After being switched on, the device displays the sensor symbol.	➢ You are not using the original oxygen sensor (the ENVITEC oxygen sensor type OOM111 (Part No. 01-00-0114)). ➢ The sensor is not connected correctly to the plug. ➢ The sensor is defective → Replace the sensor!
The display goes out shortly after the device is switched on or does not go on at all.	➢ Batteries are empty → Replace the batteries!

CAUTION
The oxygen sensor will wear out during its normal lifespan, even when the power is off. The sensor must be replaced when the proper values are not displayed during the calibration with 20.9% O2 or 100% O2, or when the measured values are not plausible (after the troubleshooting possibilities have been analysed).

4. Influencing factors

Influence of gas pressure and gas moisture:

The oxygen sensor measures the oxygen partial pressure in the gas mixture. However, the device displays the percentage oxygen concentration so that it first needs to be calibrated.

During calibration, the oxygen partial pressure of dry ambient air is equated with a volume concentration of 20.9% O_2. Depending on the absolute humidity of the measured gas, the oxygen content (oxygen partial pressure) in the gas will fluctuates slightly. This moisture influence can be neglected because the error for the entire operating temperature range between absolutely dry and saturated gas is less than 1% O_2.

CAUTION
The calibration should be carried out under the same pressure conditions as the measurements, so that pressure differences are taken into account. The pressure conditions to consider during the measurement include the gas mixture pressure, the current air pressure, and the height of the measuring location above sea level.

Influence of ambient temperature:

The influence of changes in ambient temperature is compensated for by the Quality MonO2.

Note: You should still remember that the monitor's oxygen sensor should be adjusted to the ambient temperature. Strong short-term fluctuations in the gas temperature can temporarily impair the accuracy of the displayed value.

Influence of water:

Do not completely cover the sensor or the connecting jack with water. The measured results are influenced when water is on the gas-inlet surface of the oxygen sensor.

The surface of the device can be dried with a cloth if it gets wet. We recommend that you wait until the sensor is dry before switching on the device.

CAUTION
This device may only be opened by authorized and trained technicians!

11. Setting the alarm

1. Setting the alarm limits:

- Configuring the alarm limits

Lower alarm limit:
Press the "ALARM" button once ("Low" flashes). Then press "▼" or "▲" to change the lower alarm limit.

Note: According to the safety standard, the smallest configurable value is 18!

Upper alarm limit:
Press the "ALARM" button twice ("High" flashes). The press "▲" or "▼" to change the upper alarm limit.

Note: The highest configurable value is "100"!

- Selecting the default alarm limits

Press the "AUTO SET" button for three seconds ("OFF" flashes). This sets the lower and upper alarm limits to their normalized default settings (lower alarm limit: 18; upper alarm limit: 23).

2. Setting the acoustic alarm

When the measured/displayed oxygen concentration falls below or exceeds the specified alarm limits, an acoustic signal alarm (a periodic peeping tone) is emitted.

➔ Deactivating the acoustic alarm

Press the "Mute" button to deactivate the acoustic alarm for 1 minute.

The display will show "  ".

After a minute, the acoustic alarm will sound again and the "  " icon disappears from the display.

12. EnviteC oxygen sensor

1. Operating principle

The simplified functionality of the oxygen sensor is described below.

1. The gas being measured diffuses through a synthetic membrane and dissolves in the electrolyte of the oxygen sensor.
2. The electrolyte contains two electrodes which are interconnected via an external resistor network.
3. The proportion of the dissolved oxygen is reduced at the working electrode (the cathode). In turn, the second electrode (the anode) is oxidized.
4. The resulting inner ion current causes an outer, electrical current which is proportional to the reaction of the oxygen.
5. The diffusion of gas molecules is dependent on the temperature. To compensate for this dependency, the current is converted by a thermistor resistor network into a temperature-compensated voltage.

2. Lifespan of the sensor and batteries

The Quality MonO2 consists of a measuring device and an oxygen sensor. Since the batteries and sensor are considered wearing parts, they should be replaced when the device no longer provides accurate measurements. The sensor has been designed so that, under normal usage conditions, it should last for about one year. The batteries power the unit for at least 1,100 hours of operation under normal conditions.

The following influences on wearing and ageing should be noted:

The oxygen sensor wears out regardless of whether the device is switched on. This wear depends on the temperature and the oxygen partial pressure at the gas-sensitive surface of the sensor.

The minimum lifespan (operating time) of the oxygen sensor, therefore, is related to 1% oxygen times the hours (e.g. 1,000 hours). The sensor therefore wears out more quickly if it is stored or operated under higher oxygen partial pressures.
The temperature speeds up the material conversion of the oxygen sensor and therefore influences the ageing. So, put simply, the higher the temperature, the shorter the expected lifespan.
Very dry ambient conditions also have a negative impact on the lifespan of the oxygen sensor. This is because evaporation of the electrolytes increases.

CAUTION:
Due to these circumstances, you should not store the Quality MonO2 at unnecessarily high ambient temperatures, or in very dry environments, or under increased partial pressure of oxygen.

3. Replacing the sensor

- Loosen and remove the sensor receptacle.
- Dispose of the sensor.
- Connect the new sensor and check the function.
- Carry out a calibration.

Follow the instructions concerning the sensor packaging! The sensor contains electrolyte and lead!

4. Packaging and storage

During storage, the sensor consumes the oxygen content of the gas located in the interior of the gas inlet opening. This ageing is reduced when the sensor is stored in its original packaging. After the sensor is removed from its packaging, it needs some time before it is ready to be used for measurements. This time depends on the storage time and the storage temperature. This period can last up to 30 minutes. Therefore, a calibration of the device should be carried out after the sensor has been allowed time to stabilize. Storage at a temperature between 5 – 15 °C is recommended in order to shorten the required stabilization time.

Storage:
Temperature range: -20 °C to 50 °C / Store in original packaging.

Labelling:
Product name: Oxygen Sensor
Usage: for measuring oxygen concentrations
Type: OOMXXX, XXX – consecutive type number

Manufacturer / Supplier information:

Manufacturer:
ENVITEC-Wismar GmbH, Alter Holzhafen 18, D-23966 Wismar, Germany
Telephone / Fax: 49 (0) 3841 360 1 / (0) 3841 360 222

Supplier:
DEHAS Medizintechnik & Projektierung GmbH
Wesloer Straße 112, Building M
23568 Lübeck, Germany
Telephone / Fax: 0451 80904 0 / 0451 80904 111

13. Cleaning

1. <u>Device surface</u>
   Switch off the Quality MonO2.

   Wipe the device using a damp cloth. Make sure that no liquid enters the device.

   Common cleaning agents and disinfectants are normally suitable for use.

CAUTION
Device damage: Do not use phenol-based disinfectants and peroxide compounds for disinfecting the device surfaces. Use surface disinfectant cleansers for disinfecting. For reasons of material compatibility, cleaning preparations based on aldehydes, alcohols or quaternary ammonium compounds are suitable for use. For users in Germany, we recommend using only disinfectants that are registered in the current list maintained by the German Society for Hygiene and Microbiology.

WARNING
Electrical hazards and device damage: If liquid gets inside this device, it may only be used after customer service has inspected it.

2. Accessories

Disinfection wipes for the tee, the Blender Buddy and the flow diverter:

- Use Buraton 10 F, Terralin or similar.
- First use a disposable cloth to wipe away larger areas of contamination or dirt.

Disinfection bath for the tee, Blender Buddy and flow diverter:

- Use Gigasept FF (formaldehyde-free) or similar.
- Move each part thoroughly around in the bath. Do not clean with a hard brush! Rinse well with distilled water. Allow each part to dry completely!

CAUTION
This device and its accessories should not be put in an autoclave!

14. Disposal

Defective devices and empty batteries should not put in household waste. They must be disposed of in accordance with the relevant national or regional regulations.

15. Warranty conditions

DEHAS Medizintechnik ensures that the monitor will be free of material defects or workmanship errors for the following period:

Two (2) years from delivery

If, within the applicable period, a device defect should occur, then DEHAS shall – after written notification thereof and substantiation that the device has been stored, installed, maintained and operated in accordance with the instructions of DEHAS 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 representatives of DEHAS or any retailers are 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 statement is a final, complete and exclusive statement of the contractual terms.

The current version of the DEHAS Terms and Conditions and German law are valid.

DECLARATION OF CONFORMITY

DEHAS Medizintechnik GmbH
Wesloer Straße 112, Building M
23568 Lübeck
GERMANY

CE 0482

Quality MonO2

Classification: IIb

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

We hereby declare 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: 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:
DIN EN 60601-1-2:2010
ISO 80601-2-55:2011
DIN EN ISO15223-1:2012
EN 980:2008
EN ISO 14971:2013

Notified authority:	Medcert GmbH / CE 0482
Address:	Pilatuspool 2, 20355 Hamburg, GERMANY
Certificate number:	4153GB43411109 Expiration date: 11/2016
Devices already manufactured:	Traceable by serial number
Valid from/to:	10/2015 to expiration date
Manufacturer representative:	Director of Technology
Position:	Production and Development
Date of issue:	08 October, 2015

Ihr Ansprechpartner für Vertrieb und Service:

GmbH & Co.KG
www.hvshoernla.de
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