

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1774385-1

Organization: Hamilton Bonaduz AG
Via Crusch 8
7402 Bonaduz
Switzerland

Scope: Design and development, manufacturing, distribution and service of automated in vitro diagnostic instruments for liquid handling. Manufacturing of consumables. Contract manufacturing of mechanical components for medical devices. Warehousing and logistics.


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Reason: MoldSign Signature
Location: Moldova



The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1096617 040
Effective date: 2023-08-05
Expiry date: 2025-08-04
Issue date: 2023-08-03




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EN ISO 13485:2016

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Organization: Hamilton Bonaduz AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification covers the following:

No. Facility

/01 c/o Hamilton Bonaduz AG
Via Crusch 8
7402 Bonaduz
Switzerland

/02 c/o Hamilton Bonaduz AG
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland

Scope

Design and development, manufacturing, distribution and service of automated in vitro diagnostic instruments for liquid handling. Contract manufacturing.

Manufacturing of consumables, warehousing and logistics.

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Technical specifications

Oxygen sensors

Hamilton Medical offers oxygen sensors for use with Hamilton Medical ventilators.

Oxygen sensor for HAMILTON-G5/S1, GALILEO, RAPHAEL

1/box



Product specifications

Oxygen sensor model	PN 396008
Measuring range	0% to 100% O ₂
Response time 90%	6 seconds
Accuracy full scale (2) (3)	± 1%
Accuracy over operating range (4)	± 5%
Drift % signal/month (2)	< 1%
Linearity (2)	± 1%
Temperature coefficient	Compensated
Humidity noncondensing	0% to 99% relative humidity
Expected life (1)	60 months
Storage temperature (5)	0°C to 40°C

1. In air (20.9% O₂) at 25°C and 1 atm.
2. At a constant temperature, pressure and humidity < 1% volume O₂ when calibrated at 100%.
3. For optimal performance at higher oxygen levels, calibrate with 100% oxygen.
4. Calculated from the signal output value where above, and after any step change of 15°C or more once the sensor has reached equilibrium (approximately 1 hour).
5. Sensors may be stored in up to 55°C on a temporary basis only (up to one week); for example, during transport.

Technical specifications

Oxygen sensor for HAMILTON- C3/C2/C1/T1/MR1

1/box



Product specifications

Oxygen sensor model	PN 396200
Measurement range	0% to 100% O ₂
Accuracy and repeatability	< 1% volume O ₂ when calibrated at 100% oxygen
Linearity error	< 3% relative
Response time	< 12 seconds to 90% of final value
Cross-interference	Meets ISO 80601-2-55 requirements
Effect of humidity	-0.03% relative per %RH at 25°C
Effect of mechanical shock	< 1% relative after a fall from a height of 1 meter
Temperature compensation	Built-in NTC compensation
Operating humidity	0% to 99% relative humidity, noncondensing
Long term output drift	< 1% volume oxygen per month Typically < -15% relative over lifetime
Storage temperature:	-20°C to +50°C
Prolonged lifetime	Maximum lifetime when stored between +5°C and +15°C
Warm-up time	< 30 minutes after replacement of sensor
Nominal sensor lifetime	≥ 1,000,000% volume oxygen hours

All specifications apply to standard conditions: 1013 hPa; 25°C dry, ambient air.

Technical specifications

**Oxygen sensor for HAMILTON-G5/S1,
GALILEO, RAPHAEL**
1/box



Product specifications

Oxygen sensor model	PN 396009
Measurement range	0% to 100% O ₂
Response time	< 6 seconds to 90% of final value
Accuracy	±1% full scale at constant temperature and pressure
Operating humidity	0% to 95% relative humidity
Temperature compensation error	= 5% of reading over the operating temperature range
Expected lifetime	36 months in air at 25°C, 25% relative humidity, ambient pressure

Technical specifications

Paramagnetic O₂-sensor - Upgrade kit
For HAMILTON-G5/S1 ventilators with SN
10291 or higher
1/box



Product specifications

Oxygen sensor model	PN 159715
Operating range	0% to 100% O ₂ with over range capability –15% O ₂ to +200% O ₂
Intrinsic error	< ± 0.2% O ₂
Linearity†	< ± 0.2% O ₂
Repeatability†	< ± 0.2% O ₂
Signal noise (peak to peak)†	< 0.2% O ₂
Zero stability (permanent drift from calibration value)†	< ± 0.4% O ₂ for the first 24 hours < ± 0.2% O ₂ for the subsequent week (additional) < ± 0.2% O ₂ per month thereafter (additional)
Temperature coefficient	Zero: < ± 0.5% O ₂ / 10°C Span: < ± 0.5% of O ₂ reading / 10°C
Pressure range	± 33 kPag (±5 psig), operating ± 66 kPag (±10 psig), proof ± 100 kPag (±15 psig), failure
Tilt	< ± 0.5% O ₂ equivalent for 15° change in orientation from the calibration point
Time to valid reading	Time to valid output (from startup when within environmental specifications): < 8 seconds Time to status output (from startup when outside of environmental specifications): < 8 seconds
Operating temperature	5°C to 50°C (41°F to 122°F)
Storage temperature (noncondensing conditions)	–30°C to +70°C (–22°F to 158°F)
Storage pressure	10 kPa–200 kPa (1.5 psi–30 psi)
Thermal time constant	Time required for O ₂ -signal to reach 66% of final reading after a 20°C step change in ambient temperature: 15 minutes
Ambient humidity	0% to 95% relative humidity
Altitude range (operating)	–500 m to +5,000 m (–1540 ft to +15,400 ft)

Where marked (†) testing has been conducted in accordance with the requirements of IEC 61207-1 1994.