Technical specifications

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

single use

Product specifications

Oxygen sensor model	PN 396200
Measurement range	0% to 100% O2
Accuracy and repeatability	< 1% volume O2 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 of % volume oxygen hours
Warranty period[13]	15 months from date of manufacture

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

[13] For more information, see the '*Company statement Oxygen sensors warranty*' on: https://www.hamilton-medical.com/Partner-net/.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1093044-1
Manufacturer:	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
EUDAMED Single Registration No.:	CH-MF-000013790

Digitally signed by Ceaicovschi Tudor
Date: 2025.04.30 11:08:35 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Products:

Products of class IIa:
R9099 – Respiratory and Anaesthesia Devices – Others
R020101 – Breathing Circuits, Standard
R020102 – Breathing Circuits, Coaxial
R030102 – Air/Oxygen Masks and Nasal Cannulas

Products of class IIb:
R9099 – Respiratory and Anaesthesia Devices – Others
R060201 – Humidification Systems
Active Ventilation Humidification Systems

Products of class III:
Z120301 – Instruments to Support and Monitor Vital Signs
Anaesthesia and Pulmonary Ventilation Support Instruments

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	3321004-520
Effective date:	2024-01-12
Expiry date:	2025-12-23
Issue date:	2024-01-12

Sebastian Mniszek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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www.zlg.de
BS-MDR-091

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EU Certificate

Quality Management System
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Registration No.:	HZ 1093044-1
Manufacturer:	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
EUDAMED Single Registration No.:	CH-MF-000013790
Authorized representative(s):	medin Medical Innovations GmbH Adam-Geisler-Strasse 1 82140 Olching, Germany DE-AR-000006976

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2021-09-15
1	Scope extension, Products of class IIb, add. R9099	2023-03-15
2	Scope extension, Products of class III, add. Z120301	2023-06-21
3	Scope extension, Products of class IIb, add. R060201	2024-01-12

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