

Press Release

## Airway Medix S.A. Achieves ISO 13485 Certification – Major Milestone for Quality and Growth

Warsaw, 21 May 2025 – Airway Medix S.A., a MedTech company listed on the Warsaw Stock Exchange, is pleased to announce the successful completion of Phase II of the ISO 13485 certification audit. The audit was finalized on July 18, 2025, and the company has been deemed eligible to receive the ISO 13485 Quality Management System Certificate.

The certification encompasses key areas of the company's operations, including product design and development, manufacturing, and sales of medical devices. Achieving ISO 13485 certification is a major step in ensuring compliance with regulatory requirements in key markets and reinforces the company's commitment to maintaining the highest standards of quality across all aspects of its business.

ISO 13485 – *Medical devices – Quality management systems – Requirements for regulatory purposes* – is internationally recognized as the leading standard for quality management systems in the medical device industry.

*“Successfully completing this certification process is a testament to the strength of our team and the maturity of our quality systems,”* said Anna Aranowska-Bablok, CEO of Airway Medix S.A. *“Our partners have been waiting for this certification, and now it's time to move forward with market implementations.”*

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### About Airway Medix S.A.

Airway Medix S.A. focuses on the research, development and commercialization of innovative single-use devices for mechanically ventilated patients in Intensive Care Units (ICUs), as well as life-threatening patients and anesthesiology departments. The products offered by Airway Medix address the most pressing clinical needs and fill a gap in current medical devices.



Airway Medix Solutions:

- **B-Care Oral Care** (Oral Cleaning System) – a comprehensive system for maintaining the oral hygiene of intubated and immobilized patients.
- **Cuffix – Cuff Pressure Regulator** – a system for monitoring and maintaining constant endotracheal tube cuff pressure in intubated patients.
- **Closed Suction System** – a system for cleaning the endotracheal tube in mechanically ventilated patients.
- **LMA (Innovative Laryngeal Mask)** – medical device, used to maintain airway patency in unconscious patients and in anesthesiology, R&D stage product.

Airway Medix S.A. has been listed on the Warsaw Stock Exchange since 2014.

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