

Press Release

Airway Medix Successfully Completes First Surveillance Audit, Maintains ISO 13485 Certification

Warsaw, July 20, 2026 – Airway Medix S.A., a MedTech company listed on the Warsaw Stock Exchange focused on clinical airway management solutions, announced that it has successfully passed its first surveillance audit of its Quality Management System under the PN-EN ISO 13485 standard, with a positive result and no nonconformities identified. As a result, the Company maintains the certificate issued by CeCert Sp. z o.o., an accredited certification body.

The certification covers Airway Medix's product design and development, manufacturing, and sales processes for its medical device portfolio. Maintaining ISO 13485 certification is a key requirement supporting the Company's ability to sell its medical devices across European, American, and other international markets.

ISO 13485, "Medical devices – Quality management systems – Requirements for regulatory purposes," is recognized internationally as the benchmark framework for meeting the comprehensive quality management requirements applicable to medical device manufacturers.

The maintained certification comes as Airway Medix continues to build on the transformation it completed – moving its R&D, production, and regulatory functions to Europe and shifting from a research-focused organization into a commercially driven business, with its first product reaching the market in early 2026. The Company continues to sell its products and is working to further internationalize its management structure as it grows its presence across European markets, the Gulf region, and the United States.



About Airway Medix S.A.

Airway Medix S.A. focuses on the research, development and commercialization of innovative disposable 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 in intubated and immobilized patients.
- **Cuffix – Cuff Pressure Regulator** – a system for monitoring and maintaining constant cuff pressure in endotracheal and tracheostomy tubes in intubated patients.
- **Closed Suction System** – a system for cleaning the endotracheal tube in mechanically ventilated patients.
- **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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