

Press Release

Airway Medix Advances Certification of B-Care Oral Care Medical Device

Warsaw, August 28, 2025 – Airway Medix S.A., a MedTech company listed on the Warsaw Stock Exchange, is advancing the EU certification process for the expanded version of its B-Care Oral Care medical device family under the Medical Devices Regulation (MDR). The process, expected to take approximately 12 months, will bring the product to Class IIa certification, in line with enhanced regulatory requirements. Importantly, sales of the already-approved version continue without interruption.

“This milestone highlights our ongoing commitment to development,” said Anna Aranowska-Bablok, CEO of Airway Medix. “Advancing the product to Class IIa confirms it meets higher regulatory standards. At the same time, we are commercializing our current solutions while preparing for the future. We are not resting on the success of our existing portfolio – we are building on it, continuously improving our offerings, and laying the groundwork for strategic partnership and further growth.”

B-Care Oral Care (Oral Cleaning System) is designed for intubated patients in hospitals and for homecare use. It supports safe and effective oral hygiene, helps prevent infections, and reduces the nursing workload – improving both clinical outcomes and quality of care.

Airway Medix recently obtained ISO 13485 certification, confirming that its quality management system meets global standards for medical device manufacturing. The Company is also expanding distribution partnerships to ensure broader access to its solutions.

These steps reflect Airway Medix’s strategy of combining commercialization with continuous development of portfolio, strengthening its position for further international growth in the EU, with the US as the next step.



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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