

ARTIFICIAL INTELLIGENCE DISCLOSURE

Intus.AI S.r.l. (hereinafter the “Company”) is fully committed to be transparent regarding the use of artificial intelligence in its products and services. This disclosure is issued pursuant to Article 50 of Regulation EU 2024/1689 (the EU AI Act), the Article 7 of Italian Law no. 132/2025 Art. 7, and applicable guidance from the AI Office of the European Commission.

AI System

The Company has developed Virtual Clone (ViC), a medical software intended for the visualization and processing of medical images. ViC provides functionalities that support surgeons and radiologists in the identification and segmentation of anatomical regions of interest in the thoraco-abdominal region. ViC does not provide any autonomous clinical interpretation, and all results are intended to support, not replace, the clinical judgment of healthcare professionals (hereinafter the “AI System”).

The AI System does not provide automated diagnoses; its outputs provide information used to support clinical decision-making by qualified healthcare professionals and must not replace their professional judgment.

As required by AI Act, the Company has performed the risk classification of its AI System. The Company disclose that:

- the AI System outputs must be reviewed and validated by a qualified healthcare professional before any clinical use;
- the AI System outputs are not to be used as a substitute for independent radiological or surgical judgment;
- all clinicians using the AI System are informed at system login that they are interacting with an AI system and that its outputs require professional review;
- artificial intelligence has limitations that users should be aware of.

A full description of performance characteristics, intended use, contraindications, and known limitations is provided in the Instructions for Use (IFU), which is made available to all authorized users.

Contacts

If you wish to report a concern, request information about AI-generated outputs, or exercise rights under applicable law, please contact:

IntusAI S.r.l.

Email: info@intus-ai.com

We will respond to all transparency-related requests within 15 working days. Substantiated reports of AI transparency issues will be assessed and, where warranted, trigger a corrective action process under our Quality Management System.