

Company presentation

ASTRACEC



Innovative. Reliable. Accurate

WHO WE ARE

ASTRACEC is an innovation-based company headquartered in Bologna, Italy, and operating worldwide. We design and manufacture advanced automatic machines for **Container Closure Integrity Testing (CCIT)** of pharmaceutical IV bags, built around our proprietary, patented **Probe Position Decay™** technology — accurate, reliable, non-destructive and non-invasive.

ASTRACEC retains full ownership of machine design, production and distribution, coordinating partners and suppliers while ensuring regulatory compliance throughout the entire process.

ISO 9001

Certified quality
management system



— MISSION

To provide pharmaceutical customers with the most advanced and reliable Container Closure Integrity Testing (CCIT) solutions on the market. Our customer-centric approach gives us the flexibility to tailor every system to the real conditions of each production line.

— VISION

ASTRACEC was founded to answer the pharmaceutical industry's growing need for IV-bag leak testing that is non-invasive, non-destructive and applicable under real production conditions — in particular, to meet the requirements of the new **EU GMP Annex 1 (2022)**. With this goal we developed Probe Position Decay™, a proprietary technology engineered exclusively for IV bags, overcoming the limitations of other methods available on the market.

PROBE POSITION DECAY™ TECHNOLOGY

Probe Position Decay™ is a new, patented, non-invasive and non-destructive method for leak detection on filled and closed flexible containers. It is an **evolution of the already pharma-approved Lid Deflection technology**, sharing the same regulations and acceptance procedure.

1 μm

Minimum leak dimension detectable.

≈7 s

Indicative time to detect a 10 μm defect. Cycle times depend on the application and are assessed case by case.

— KEY ADVANTAGES

- Higher leakage sensitivity
- Shorter analysis time
- Lower energy consumption
- Lower noise emission
- Gas, liquid and solid leakage detection
- Whole-container analysis
- Pressure test on container ports and connections
- Suitable for oily and non-conductive liquids
- Suitable for complex-shaped and multi-chamber bags
- Detects droplets on external surfaces (e.g. after autoclave sterilization)
- Analysis of bags inside secondary over-wrap packaging

COMPLIANT WITH

EU GMP Annex 1 - 2022

Manufacture of Sterile Medicinal Products

USP <1207>

Packaging Integrity Evaluation

ASTM F2338-09

Non-Destructive Leak Detection

PDA TR No. 27

Pharmaceutical Package Integrity

PLANT, TEAM & NETWORK



— IN-HOUSE MANUFACTURING

Our production plant covers a total area of **600 m²**. All assembly and testing activities are carried out in-house, giving our customers solid technological know-how together with fast delivery and responsive maintenance.

— AN EXPERT TEAM

ASTRACEC brings together **technicians with decades of experience** across every discipline — software, mechanical assembly, installation and commissioning. We operate within the **Packaging Valley**, one of the sector's leading industrial hubs, drawing on a consolidated network built on decades of specialist expertise.

This network enables the effective management of complex, multi-site projects with a high degree of organizational flexibility, ensuring the right resources, expertise and response times for each project — with continuous support throughout the machine lifecycle. ASTRACEC serves customers **worldwide** and, through its partnership with **Svan Analytical Instruments Pvt. Ltd. (SVAN)**, maintains a **solid local presence in India** for validation, assistance and maintenance.

600 m²

In-house production
plant

Decades

of specialist experience

India

Direct local presence

Turnkey

Full lifecycle service

Proven in the field

ASTRACEC has already completed installations and validations with leading players in the pharmaceutical industry — delivering turnkey systems, full validation and reliable lifecycle support across demanding regulated environments.

MACHINE PORTFOLIO

Two platforms built on the same Probe Position Decay™ technology, covering the full range of production needs — from off-line laboratory and low-volume testing to fully automated 100% in-line control.



POLAR OFF-LINE

Stand-alone automatic leak-testing machine optimized for off-line testing, addressing low-to-medium throughput requirements in regulated pharmaceutical environments. Compact, low-noise and heavy-duty — suitable for both the laboratory and the production floor.

Sensitivity: down to 1 µm

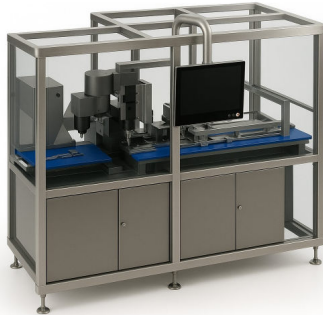
Cycle: down to 4 s

Content: solid / liquid / gas

Up to 30 L

Footprint: 0.6×0.9 m

Height: 2 m



VEGA IN-LINE

Fully automated in-line line for 100% production control, optimized for downstream integration and high-throughput environments. Robot loading from a conveyor in random order, automatic rejection of non-compliant products and a freely configurable number of analysis stations.

Sensitivity: down to 1 µm

Rate: up to 8000 products/h

Bag sizes: 3 ml–30 L

Content: liquids & gases

Feeding: right or left

SHARED ACROSS THE RANGE

FDA 21 CFR Part 11

PDF reports with statistics

SCADA connectivity

Touchscreen HMI

Automatic diagnostics

Direct remote assistance

RFID size parts

Vision system & code reading

Cleanroom ISO Class 7 certifiable

TURNKEY SERVICE & SUPPORT

ASTRACEC delivers a complete **turnkey package**. We start with feasibility studies and demonstration tests on your own products, handle installation and full validation, and support the entire machine lifecycle with predictive maintenance and direct remote assistance from our technical department.

01

FEASIBILITY & DEMO

Feasibility studies and demonstration tests run on your specific products.

02

INSTALL & VALIDATE

Installation and full validation, with documentation aligned to your regulatory framework.

03

LIFECYCLE SUPPORT

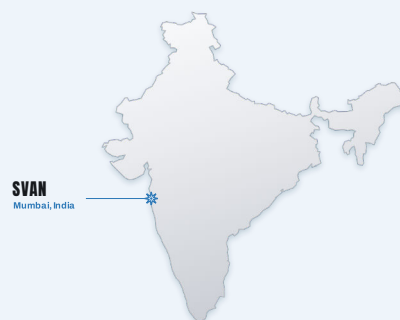
Predictive maintenance that keeps the machine performing reliably over its whole life.

GLOBAL PRESENCE

— SOLID LOCAL PRESENCE IN INDIA

Through our partnership with **Svan Analytical Instruments Pvt. Ltd.** — an established pharmaceutical-industry partner based in **Mumbai** and active in India since 2008 — ASTRACEC offers a solid, on-the-ground presence in India for **validation, technical assistance and maintenance**, with fast local response times throughout the machine lifecycle.

In partnership with **Svan Analytical Instruments Pvt. Ltd.** ·
www.svan.in



Test it on your product.

Request a feasibility study or an on-site demonstration — we'll show Probe Position Decay™ on your own IV bags.

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ASTRACEC SRL UNIPERSONALE

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