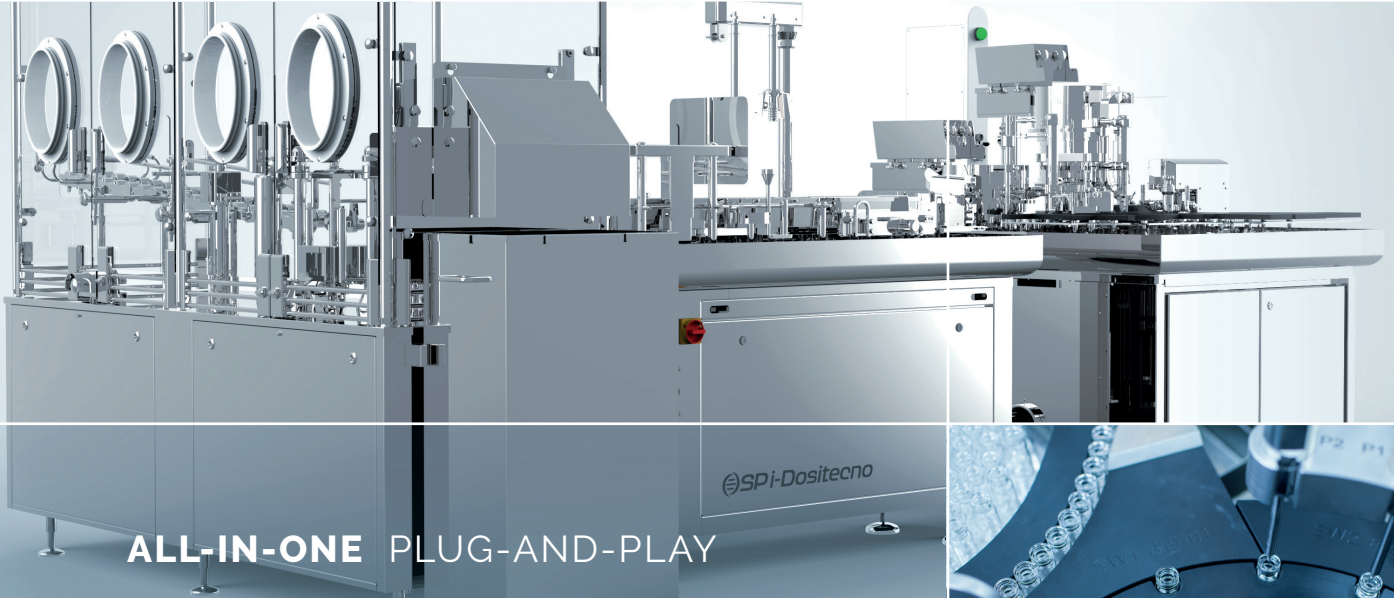


A-MICRO BI

HIGH QUALITY ROTARY FILLING SYSTEM



ALL-IN-ONE PLUG-AND-PLAY



Simple installation



Compact dimensions



Easy to use



Optimal Cost/Quality



Fast changeover

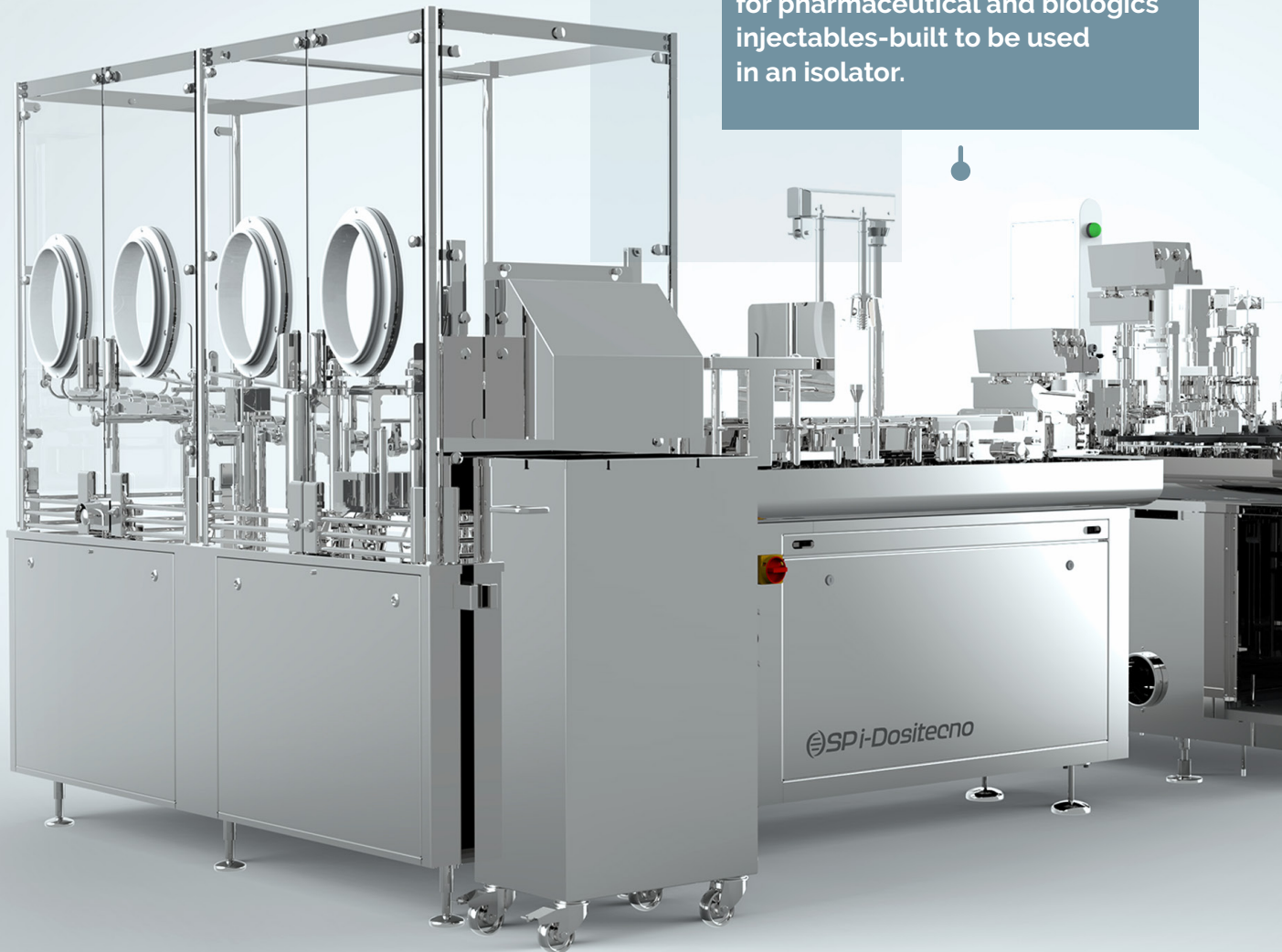


A-MICRO BI

HIGH QUALITY ROTARY FILLING SYSTEM

SP i-Dositecno A-MICRO BI

Rotary filler for the clinical and early stage pharma production specialist for fill and finish advanced aseptic manufacturing for pharmaceutical and biologics injectables-built to be used in an isolator.



FILLING LINE main features

This unit offers a minimized starwheel in tandem with dialed in servo control and flexibility. Trayed vials and/or nested vials/syringes/cartridges are introduced for fill finish. Vials are weighed/filled and closed (stoppers and optional caps.) 2 up filling alternatives give the user a range of outputs and flexibility. The pre-designed units can be set up both "isolator ready" and open RABS configurations.

Full Servo design incorporates filling precision and repeatability, product conservation and closing systems with great process windows. The SP internal core competencies include excellent glass handling/ fluid dynamics skill sets and automation practice. The machinery is very friendly for cleanability and ISO 5 air flow practice. Easy changeovers and easy touch screen interface; Modern Documentation and validation support.

Base Unit Equipment

- 1 or 2 Filling Pumps fully integrated with IDT scale algorithm with auto feedback to peristaltic pumps. Piston pumps available upon request
- One size part set for each type of closure with base machine (up to 2)
- Central machine starwheel performs all functions- filling and closing and optional items.
- Baseline Keba controls for motion control/AB or Siemens PLC optional, PC based touch panel screen
- Other options available

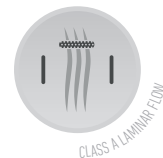
Comecer Isolator

The isolator is designed in order to grant aseptic conditions inside the machine process area and to protect operators from product toxicity.



ISOLATOR main features

- Filtration grade with H14 filters IN / OUT
- Exhaust fans positioned in the technical area
- Automatic Shutter gates, for IN / OUT for differential pressure & containment control
- LED lighting, positioned on the outside of the aseptic process area
- Doors with 12 mm thick tempered glass with inflatable gaskets
- Glove ports with independent safety barrier
- Integrated Glove Integrity Tester with Speedy Glove
- Return ducts for optimal uniformity of the air flow
- Bag-In Bag-Out filtration upon request
- Isolator walls made of 3 mm thick stainless steel AISI 316L with internal finish Mirror Brite <math>< 0.3\mu\text{m}</math> and round corners of 20 mm radius
- Spray Balls and Spray guns for facilitating the cleaning of the unit at the end of the production
- Integrated Comecer VPHP generator for automatic decontamination of the equipment
- Isolator & filling machine together will satisfy the containment level Class 3, ISO 10648-02. Leak rate <math>< 1\%</math>



A-MICRO BI

HIGH QUALITY ROTARY FILLING SYSTEM

Technical data:

- Output up to: 3,000 u/h
- Vial size 2R - 50R: 0,1ml - 250 ml
- Additional elements: cRABs, oRABs, Isolator, LAF
- Documentation: DQ, IQ, OQ

Additional items included:

- Vials reject
- Advisor lights
- DQ
- oRAB's
- CFR21 part 11

Optional equipment:

- IPC 100% weight control
- Laminar Flow (LAF)
- cRABS, Isolators
- IQ, OQ
- VPC and NVPC integration
- Settle Plates support
- Modes: Capping only, fill stopper only; fill and stopper cap; single and dual head versions;
- Larger peristaltic pumps & Piston Pump conversions
- Cap Crimping Stations (idler wheel) and size part set ups
- N2 Gassing, during and after filling
- Product conservation Modes
- Vial, stopper finish and cap finish options; single and dual closing station options
- Pre-feeding systems for stoppers and caps
- Dual laser detection for raised stoppers
- Single use custom set
- 5/8 liter SS-316 intermediate tanks with integrated scales
- Validation package



ATS Life Sciences is an industry-leading manufacturing automation provider to customers requiring CGMP compliance, performance, and reliability. We have a world-class team, and an enviable portfolio of standardized and custom products, smart conveyance platforms, synchronous and asynchronous technologies, robotic solutions, and material handling systems.

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Comecer is a leading provider of innovative, high-tech systems in the field of aseptic processing and containment for the pharmaceutical and nuclear medicine industries, specializing in isolation technology solutions for regenerative medicine and tissue engineering. Comecer offers modular or customized isolators to best fit processes like drug compounding, aseptic vial and syringe filling, sterility testing, and to cell and gene therapy.

comecer@comecer.com



SP covers the complete range of aseptic processing tools and techniques, from cycle development, stability testing, pilot and clinical batch production through to full aseptic manufacturing and commercial production batches. Our expertise in processing and packaging is matched with in-depth software engineering capabilities and customer-orientated servicing and support.

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