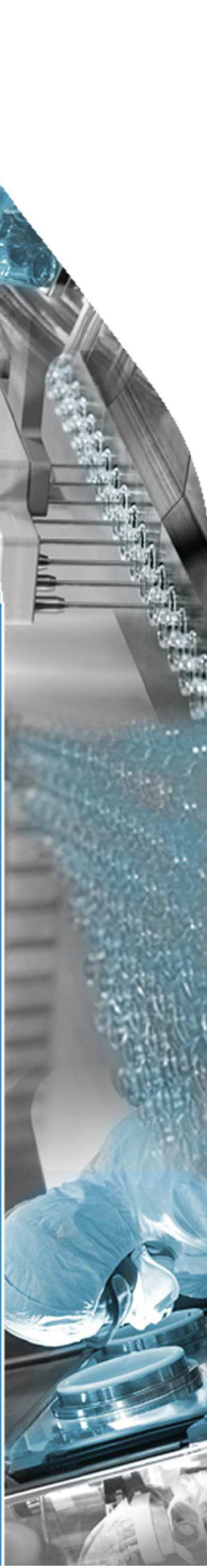




Desafios e modernas soluções na fabricação de medicamentos injetáveis

Soluções de preenchimento / acabamento para manufatura flexível/
Fill/finish solutions for flexible manufacturing



November 2018

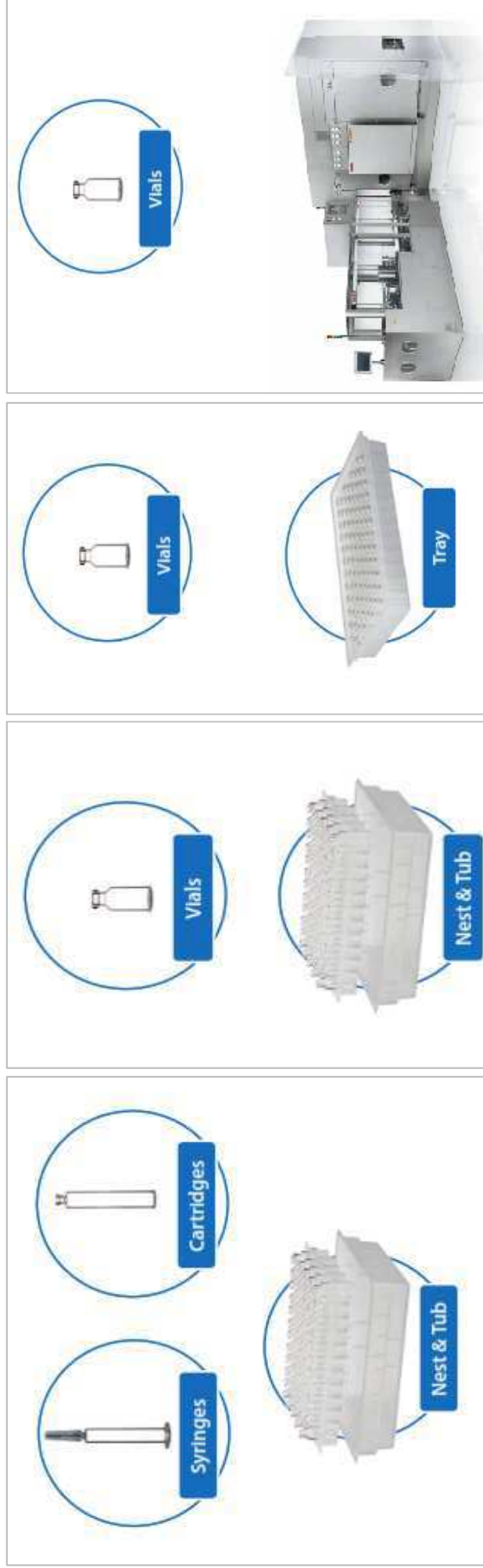
IMA LIFE CONTENTS

The aseptic filling market is actually exploding, with a variety of applications in terms of fill sizes, vial types, and compatibilities .

Current market trends in aseptic fill-finish are now forcing pharmaceutical companies to adopt agile manufacturing strategies and embrace new technologies to meet the actual requirements for a highly variable production process.

Central goal is to achieve flexible production in a safe, aseptic environment, implementing cost-saving solutions with a space-efficient design.

To achieve the aim of reaching the maximum possible improvement in safety and productivity **the full fill/finish process should be completely based on robotics operating in a closed, gloveless, isolator environment.**



IMA LIFE CONTENTS

- [STERI LIF3](#)
 - ✓ *Small batches filling and stoppering machine for RTU syringes, vials and cartridges*



- [STERIFILL RS Series](#)
 - ✓ *Medium speed filling and stoppering machine for RTU syringes, vials and cartridges*



- [INJECTA](#)
 - ✓ *Medium high speed filling and stoppering machine configuration for for RTU syringes, vials and cartridges*





Fully automatic, highly flexible filling and stoppering machine to efficiently fill nested syringes, vials, and cartridges, ideal for small batch production.



- Very precise filling operations for high product yield
- Multiple dosing options
- Easy upgrade with automated upstream and downstream processes (de-bagger, de-lidder, de-nester, re-nester, etc.)
- Integrated capping station for vials
- Completely rushless driven
- Ideal to be exposed to H₂O₂ (Hydrogen Peroxide in Vapour phase)
- Compact design



- **OPTIONALS**
- Fully automated 100% & Statistical IPC
- Nitrogen Gas Purging Unit
- Vacuum Filling System for viscous products to avoid air bubbles
- CIP/SIP systems
- oRABS, cRABS or Isolator integration
- 21 CFR Part 11 compliance



OUTPUT

- Up to 1.500 pcs/h
- Up to 1.000 pcs/h with 100% IPC





Fully automatic small batch filling & stoppering machine for ready-to-use pre-sterilized nested syringes and vials in a tub (BD Hypak or equivalent)

OUTPUT:

- Up to 4.800 syringes/hr (2 pumps)
- Up to 12.000 syringes/hr (5 pumps)

**OPTION**

- automatic extraction of nest from the tub and positioning under the filling/stoppering station and re-insertion available
- Nitrogen Gas Purging Unit
- Vacuum Filling System for viscous products to avoid air bubbles
- 100% & Statistical IPC
- CIP/SIP systems
- UAF and cRABS integration
- Pre-arranged for Isolator
- 21 CFR Part 11 compliance

- Very neat, clean & compact design
- All product contact parts in AISI 316L
- Easy access for the operator
- Touch screen HMI
- Siemens PLC

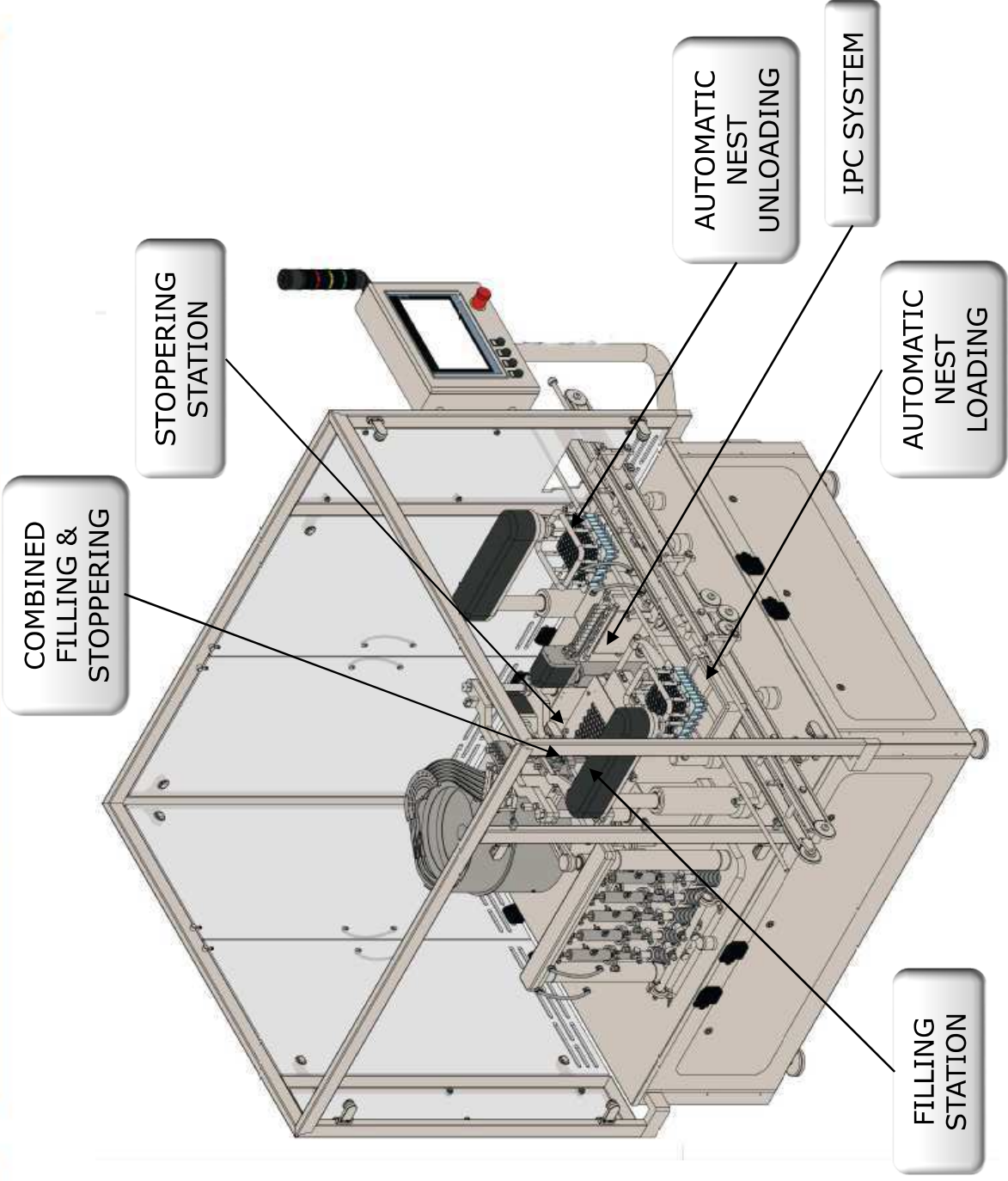


STERIFILL RS-P2V

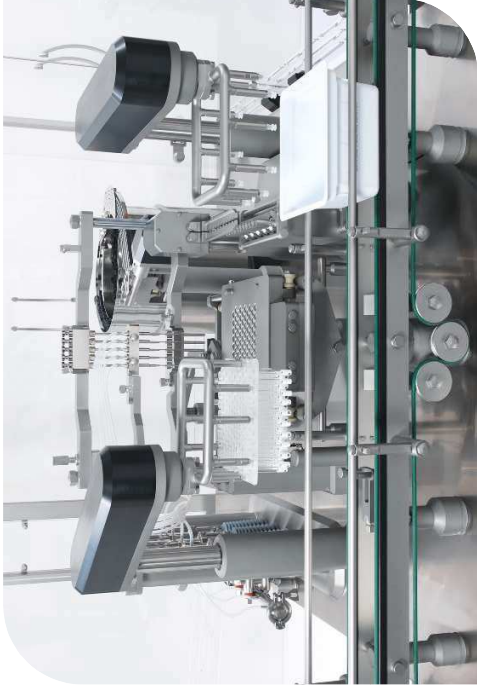
Syringe filling & stoppering machine



Syringe	Syringe in Nest	Output (2 Pumps)	Output (5 Pumps)
0,5 ml	160	4800	12000
1 ml	100	4300	12000
1 ml L	100	3800	11000
3 ml	100	4300	10000
5 ml	64	3200	8000
10 ml	42	2200	5000
20 ml		30	
Syringe diameter		8 - 22 mm	
Weight		1000 Kg	
Voltage		400 V - 50 Hz - G	
Installed power		15 kW	



AUTOMATIC LOADING AND REMOVAL OF NESTS



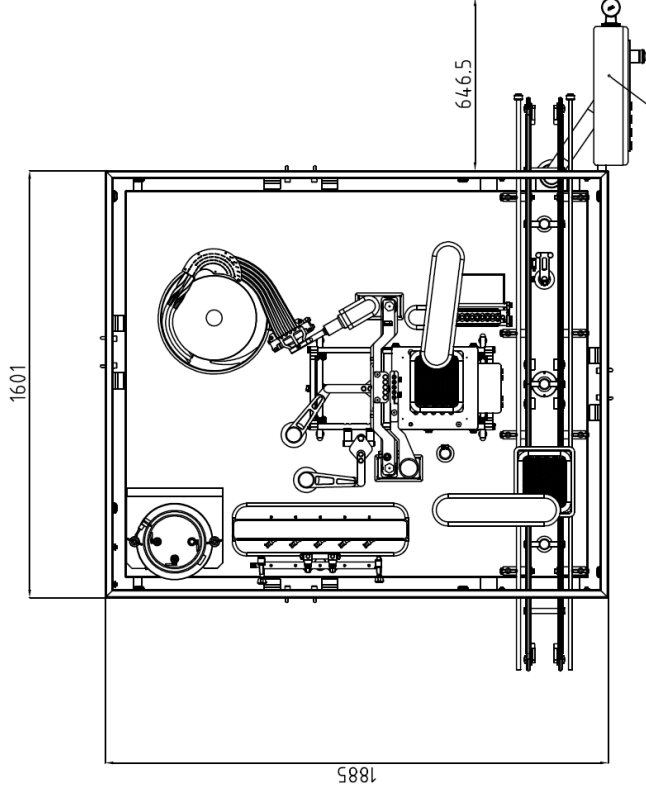
Automatic extraction and positioning of the nest on the nest holder and automatic re-insertion station to place the nest back in the tub.



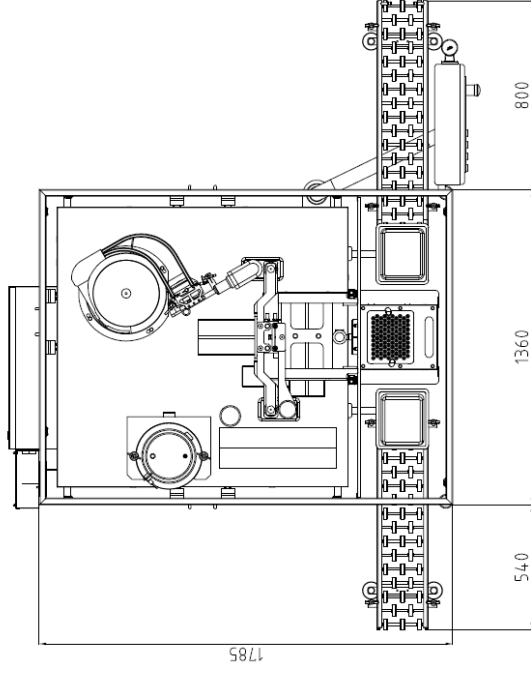
FULLY AUTOMATED 100% AND STATISTICAL CHECK WEIGHING SYSTEM



A pushing unit extracts the empty syringes from the nest, then a mechanical arm, driven by two servo motors, places them on to individual weigh cells to resolve the tare weight of each syringe. The syringes are reinserted into the nest for filling and stoppering. They are then weighed again in the same way. Electronically controlled scales determine the tare and gross weights and calculate the effective net weight by difference. The IPC system controls the automatic self adjustment of the dose within the pre-set tolerance limits.



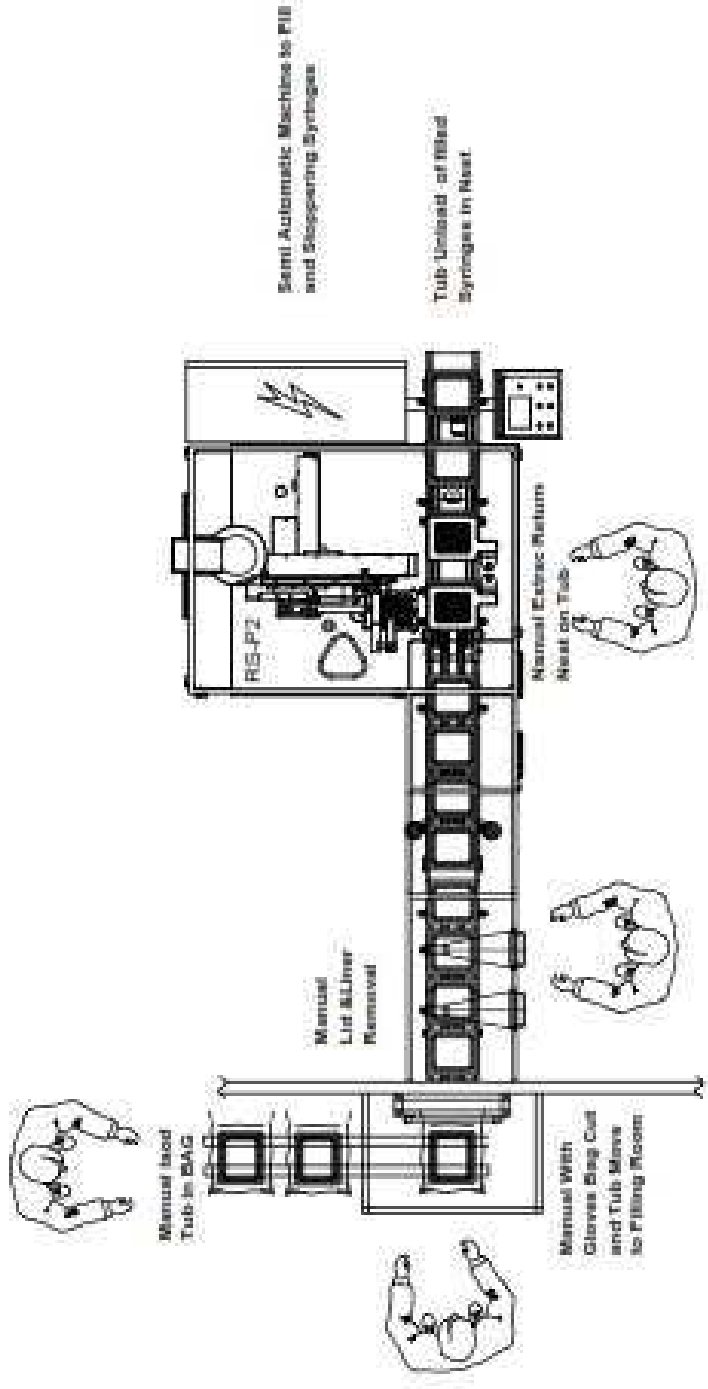
STERIFILL RS-P5



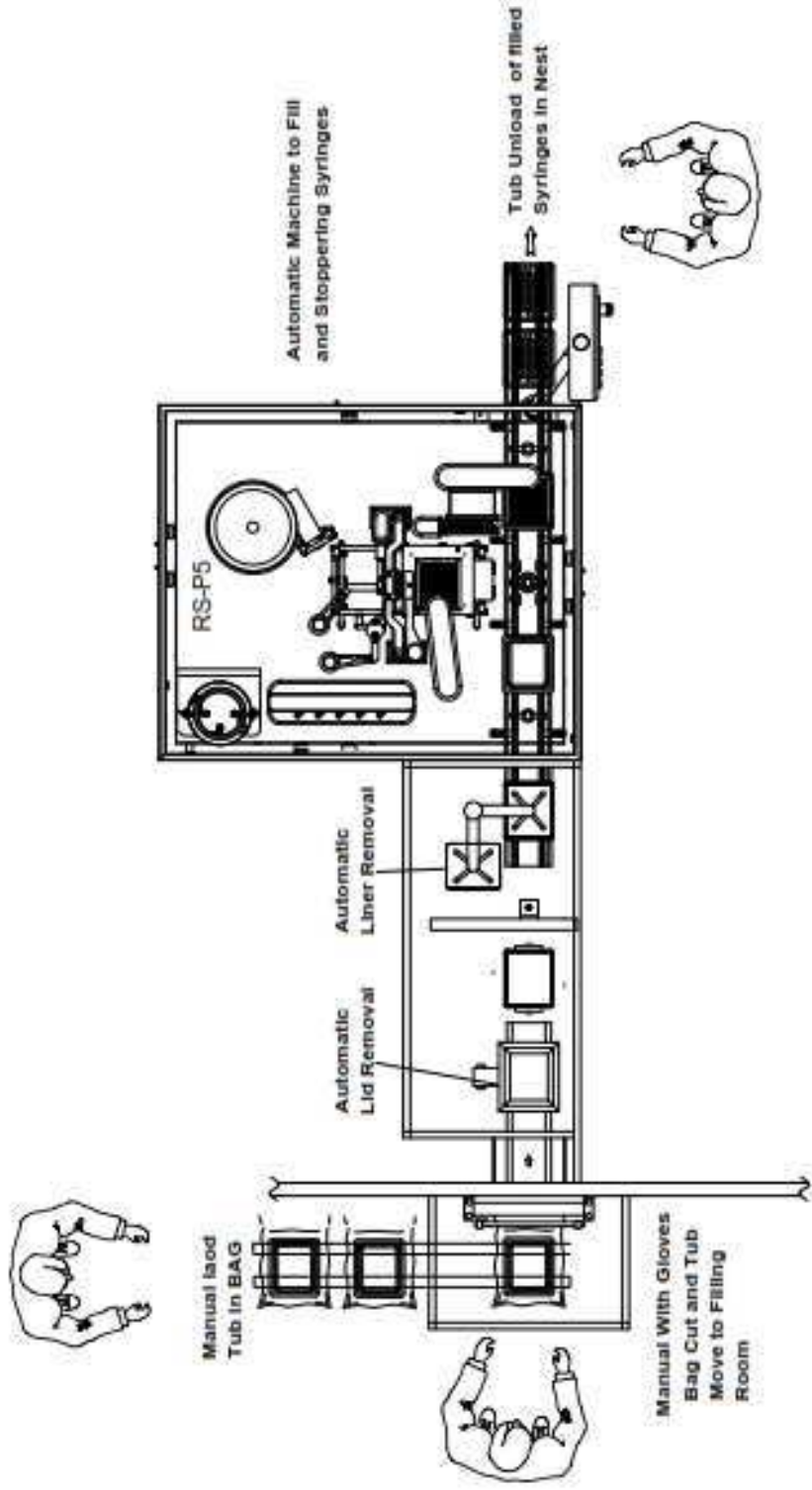
STERIFILL RS-P2



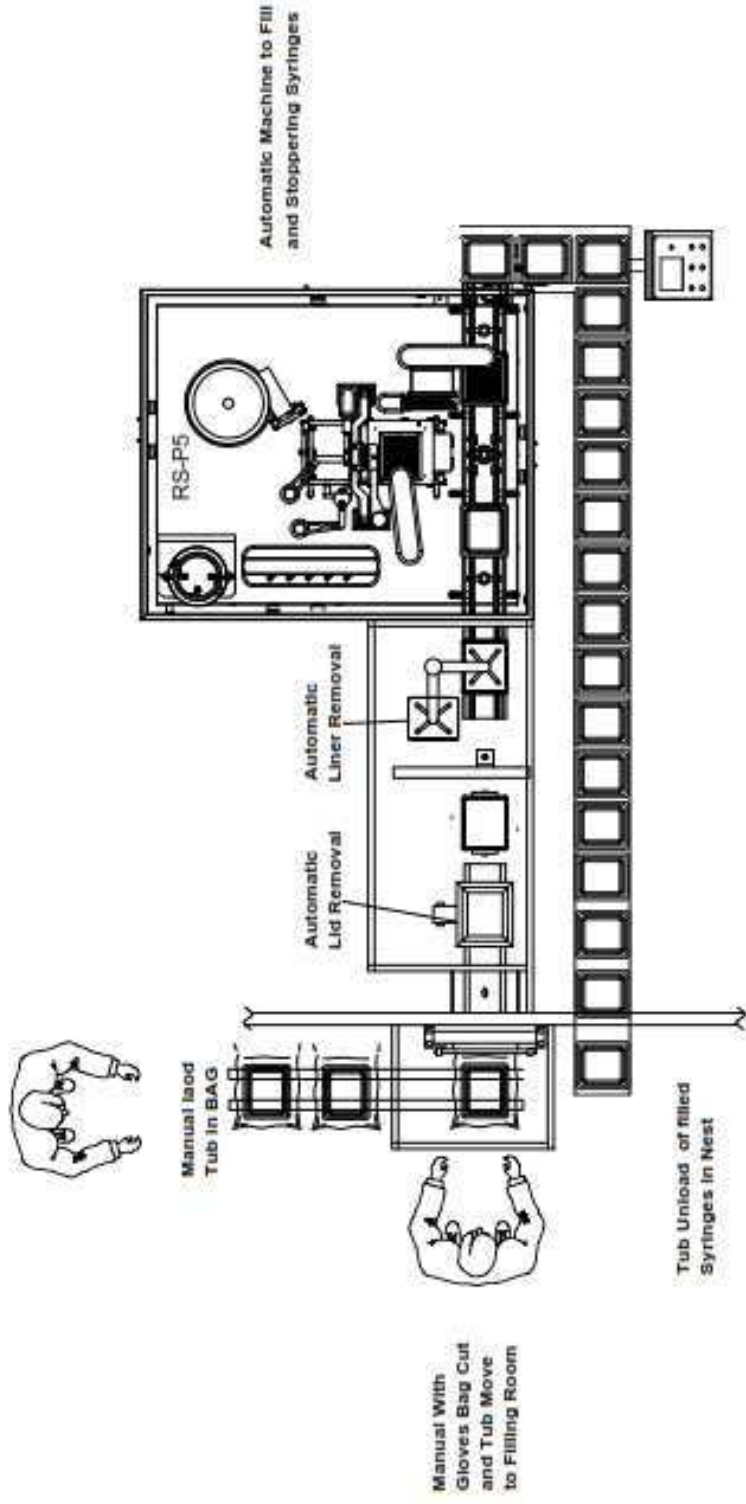
SEMI AUTOMATIC SYRINGE FILLING & STOPPERING LINE SPEED UP TO 6.000/h



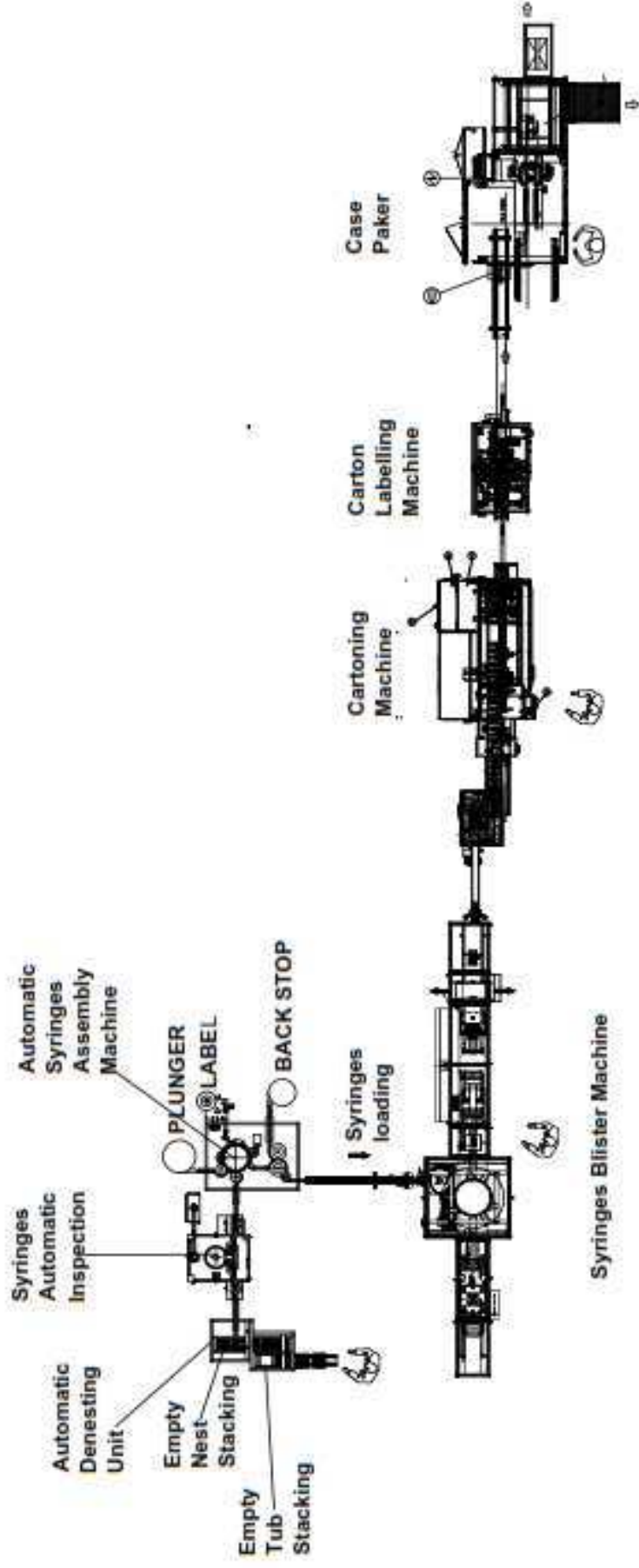
AUTOMATIC SYRINGE FILLING & STOPPERING LINE SPEED UP TO 12.000/h



AUTOMATIC SYRINGE FILLING & STOPPERING LINE («U» CONFIGURATION) SPEED UP TO 12.000/h



SYRINGE PACKAGING LINE
200 CARTONS/min





- Injecta 3D COMBI overview
- Injecta Combi - nested components lay out
- Injecta Combi – denesting + lyo lay out
- Production table
 - ✓ RTU nested components
- Video

