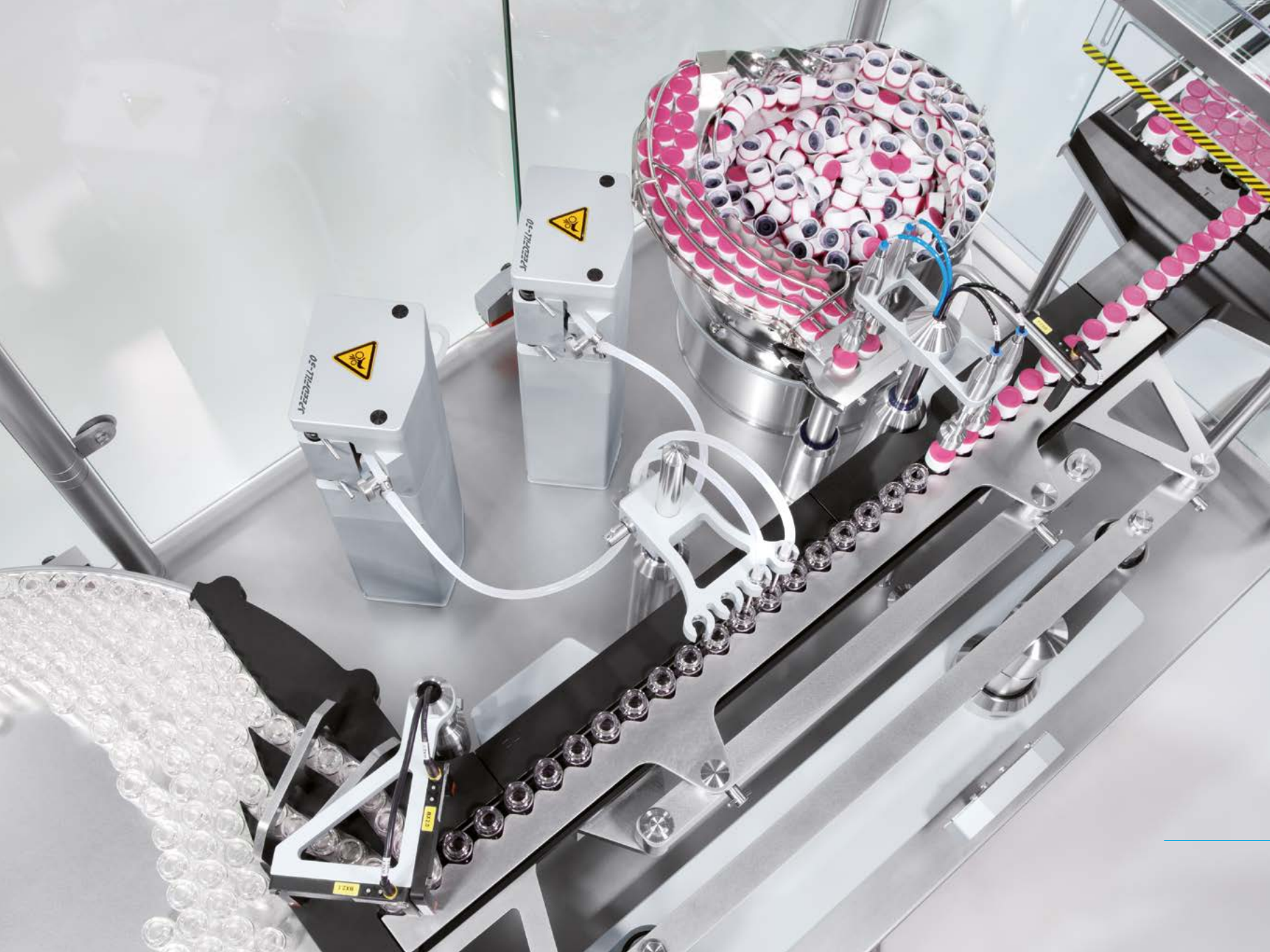
Dara
Pharmaceutical Equipment

RayDyLyo®

# SX-310-RDL

Compact machine
for automatic infeed,
filling, and closing
of injection vials and
RayDyLyo® caps.

Vials



Filling from 0.1 ÷ 250 ml | Filling system 100% weight control

Output up to 7,200 uph | Conforms with cGMP - US FDA

*Liquid filling*

# SX-310-RDL

**Compact machine for automatic infeed, filling, and closing of injection vials and RayDyLyo® caps.**

The equipment we present is a compact filling and closing machine for automatic processing of cylindrical vials in glass, plastic, or metal, for liquid, semisolid, and powder products, in sterile areas.

Suitable for RTU vials (ready-to-use) as well as for vials supplied in bulk.

The design has been made in compliance with the regulations of cGMP and US FDA, and in special accordance with the pharmaceutical, biotech, cosmetic, chemical and similar industries.

Output up to 7,200 uph.

The filling station can be equipped with valveless rotary piston pumps, made of stainless steel or ceramic, or with SpeedFill® peristaltic pumps for liquid products, and with vacuum-pressure fill guns for powders.

When using CIP / SIP construction elements, it is not necessary to remove the product contact parts for their cleaning or sterilization.

All dosing recipes can be saved and, therefore, can be later retrieved from the control panel.

Production parameters, such as dosing volume or the kinematics of the filling system, are saved in the PLC. New recipes can be quickly and easily created.

For dosing volumes from 0.1 to 250 ml.

*The placement of the RayDyLyo® caps with the pre-assembled rubber stopper is done with a vacuum handling pick & place.*

# SX-310-RDL

## CLOSING

RayDyLyo® caps offer multiple benefits:

Elimination of the crimping process for injectable liquid and freeze-dried forms:

- All-in-one solution: plastic cap and preassembled stopper. For ISO 8362-1 vials and ISO 8362-2 rubber stoppers.
- Rubber stoppers are defined by the customer and pre-assembled automatically in the RayDyLyo® cap prior to the distribution on line.
- Vial closure by simple vertical pressure.
- Reduction of all risks of environmental contamination on the distribution lines.
- Risk reduction of stoppers adhering to the freeze-dryer plates.
- Reduction of "pop-off" effect.
- Simplification and time-saving on freezedrying operations.

Wide range of caps is available:

- Diameters of 13/20 mm in different colors.
- Closure system available in CTO (Central Tear-Off) and TTO (Total Tear-Off).

Sterilization:

- Different sterilization modes (Gamma or Autoclave).

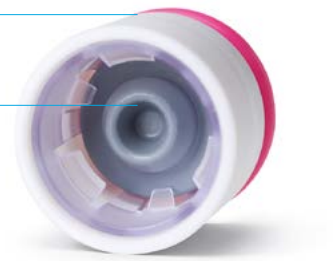
Ergonomics of the device:

- Easy cap removal.
- Reduction of risks of damaging gloves.

*RayDyLyo® Cap*

*Rubber stopper*

- *Lyo*
- *Injectable*



*Feeding of different types of RayDyLyo® caps is done automatically, through AISI-316L vibrating feeders.*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# SX-310-RDL

In order to work in sterile applications, Dara Pharma provide tailored solutions, such as LAF (Laminar Air Flow) and RABs (Restricted Access Barrier Systems). The generated vertical flow of sterile air ensures a permanent and reliable expulsion of particles and microorganisms from the working area.

With an integrated isolator, the sterile area is reduced to the area of the filling and closing machine, that allows the equipment to operate in a clean room class D, complying with the regulations of the pharmaceutical industry.

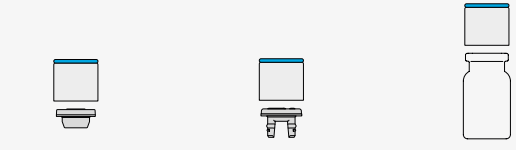
*Compact machine to process RTU vials. Design adapted to work under laminar flow conditions.*

# NFL/2-RDL

## Optional equipment

- Washing unit and sterilization tunnel for vials supplied in bulk.
- Dosing control of 100% of processed vials through electronic weighing scales.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Vacuum-assisted positioning of caps to reduce the presence of oxygen in headspace.
- Automatic rejection of defective vials.
- Process data acquisition software in accordance with FDA 21CFR Part 11.
- Particle monitoring and counting.
- Vial output onto a double tray.
- Laminar flow unit / RABs / Isolator unit.
- IQ / OQ validation package.
- Printing / Codification.

*Filling and RayDyLyo® caps positioning on vials.*

| Model | SX-310-RDL | |
|---|---|---|
| Max. output / uph: | 3,600 uph | 7,200 uph |
| Container dimensions: | Ø 65 mm max.<br>h 210 mm max. | Ø 36 mm max.<br>h 75 mm max. |
| Filling product: | Liquid pharmaceuticals (solutions and suspensions) | |
| Type of closures: | RayDyLyo® cap Ø 13/20 mm | |
| Dosing range / accuracy: | 0.1 ÷ 250 ml / ±0.5% | |
| Electrical supply: | 230/400 VAC – 50/60 Hz – 3 kW max. | |
| Max. weight: | 610 kg | 720 kg |
| Materials: | AISI-304 stainless steel, anodised aluminum, POM and contact parts with product in AISI-316L stainless steel | |
| Environmental conditions: | Temperature 5 ÷ 40 °C / Relative humidity 70% max. / Altitude 1,500 m max. | |
| Format range: |  RayDyLyo® cap with pre-assembled lyo stopper<br>RayDyLyo® cap with pre-assembled injectable stopper<br>Vials | |

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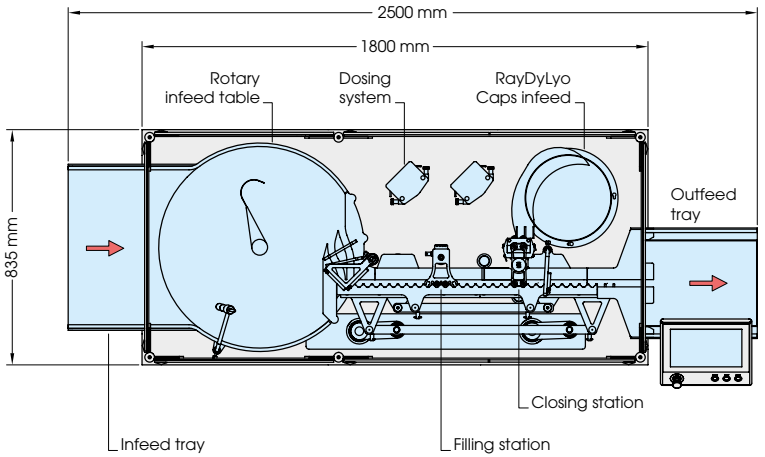


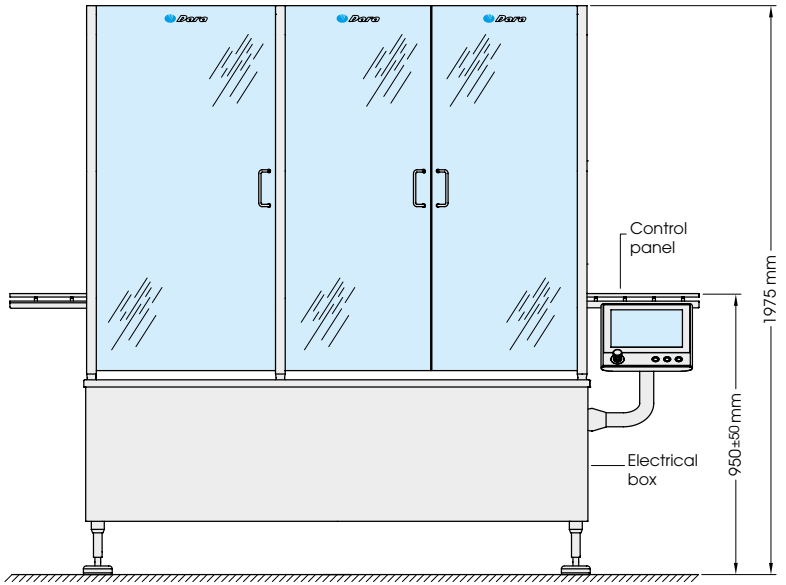


Subject to technical modifications.
Please note that the illustrations may vary from the standard version in some details.

*Flexibility in motion*

Dara Pharmaceutical Equipment

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