

**FILL FINISH**  
Technology



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## Product overview

# Product portfolio

Machine type	Container	End product
STANDARD RANGE		
Rotary washing machine RA-RC	vials - ampoules - cartridges	liquid - lyo - powder
Depyrogenation tunnel ST	vials - ampoules - cartridges	liquid - lyo - powder
Filling machine VFM	vials - syringes	liquid - lyo
Capping machine VCM	vials	liquid - lyo - powder
External decontamination machine EDM	vials - ampoules - cartridges	liquid - lyo - powder

ROBOTIC RANGE		
Vial filling machine RVFM	vials	liquid - lyo
Vial capping machine RVCm	vials	liquid - lyo - powder
External decontamination machine EDM-RHP	vials	liquid - lyo - powder
Tray loader RTL	vials - cartridges	liquid - lyo - powder
Tub decontamination system RTDS2	tubs	liquid - lyo - powder
Nest filling machine RNFM	vials - cartridges - syringes	liquid - lyo

Machine type	Container	End product
CONTAINMENT AND ISOLATION		
LAF and oRABS	vials - ampoules - cartridges syringes	liquid - lyo - powder
In-line cRABS and isolator	vials - ampoules - cartridges syringes	liquid - lyo - powder
Stand-alone isolator	vials - ampoules - cartridges syringes	liquid - lyo - powder

INTELLIGENT COMPOUNDING SYSTEM		
Intelligent compounding system	syringes - i.v. bags - bottles - elastomeric infusors	liquid

# Customer service

- 1 **After-sales services**  
Include all the activities needed to fix any technical problem in the shortest time possible, from the registration of the request received by the client to the coordination of the different teams to be involved in the problem solving.
- 2 **Technical training**  
Organized training sessions held at company HQ in Como, Italy by our team of experts. Additional follow up training and information sharing can be completed on location at customer site.
- 3 **Technical audits**  
Steriline Customer Service can handle requests to perform technical audits that will be executed by experienced mechanical, software and electrical engineers.
- 4 **Software services**  
Thanks to new technologies the Steriline software team can remotely access customer machines (equipped with the appropriate hardware and software) to diagnose and fix any problem in short order.
- 5 **Spare parts**  
Steriline can offer:
  - The fastest components supply service
  - The highest quality material in the market
- 6 **Refurbishing**  
The possibility to revamp your old Steriline machine/line to the latest technology.
- 7 **Preventive and strategic maintenance**  
Accurate planning of periodic visits performed by Steriline specialists.
- 8 **Pharma services (qualification/validation assistance on-site)**  
IQ, OQ, PQ and other protocol preparation and execution assistance according to the GMP rules.
- 9 **Personnel training**  
Steriline engineers to support customers' learning processes.

- In addition to our customer service activities, microbiological and analytical works can be either included in the single project or managed independently to satisfy our customers' requirements.
- Machine on-board component calibration and setting**  
With this activity, before the machine installation, each single component is calibrated and set providing a turn-key solution including:
- Temperature probes
  - Pressure transmitters
  - Pressure differential indicators
  - Thermo-couples
- Machine hardware component calibration and setting**
- Inverters
  - PLC
  - Servomotors
- Machine protocol execution support at FAT and on-site:**
- Process tests (vial cleaning capacity, filling capacity, thermal cycle, air speed uniformity, vaporized H<sub>2</sub>O<sub>2</sub> decontamination, particle counter integration, etc.)
  - Performances tests (machine output, production speed, etc.)

# Laboratory work

# Standard range



## Rotary washing machine RA-RC

### Key features

- ◆ Capacity up to 24,000 pcs/h
- ◆ Range 2R-100H vial, 1-10 ml ampoules, 1-3 ml cartridges
- ◆ Quick changeover



## Depyrogenation tunnel ST

### Key features

- ◆ Compact design
- ◆ Constant performance output along product lifecycle
- ◆ Energy saving



## Filling machine VFM

### Key features

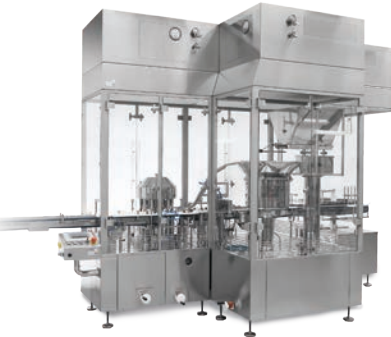
- ◆ Capacity up to 24,000 pcs/h
- ◆ Range 2R-100H vial
- ◆ Quick changeover



## Capping machine VCM

### Key features

- ◆ Capacity up to 24,000 pcs/h
- ◆ Range 2R-100H vial
- ◆ Quick changeover



## External decontamination machine EDM

### Key features

- ◆ Capacity up to 48,000 pcs/h
- ◆ Range 2R-100H vial, 1-10 ml ampoules 1-3 ml cartridges
- ◆ Quick changeover



## Ancillary equipment

- De-bagger
- De-lidder
- De-liner
- De-nester
- Tray loader





## Robotic range



### Vial filling machine RVFM

#### Key features

- ◆ Capacity up to 6,000 pcs/h
- ◆ Range 2R-200H
- ◆ Minimum downtime



### Vial capping machine RVCM

#### Key features

- ◆ Capacity up to 6,000 pcs/h
- ◆ Range 2R-100H
- ◆ Minimum downtime



### External decontamination machine EDM-RHP

#### Key features

- ◆ Capacity up to 3,000 pcs/h
- ◆ Range 2R-500ml
- ◆ Minimum downtime



### Tray loader RTL

#### Key features

- ◆ Capacity up to 36,000 pcs/h
- ◆ Range 2R-100H
- ◆ Quick changeover



### Tub decontamination system RTDS2

#### Key features

- ◆ Up to 2 tubs per minute
- ◆ Suitable for all kinds of tubs and also available for trays
- ◆ No format change



### Nest filling machine RNFM

#### Key features

- ◆ Capacity up to 18,000 pcs/h
- ◆ Range "all available nests"
- ◆ Minimum downtime



## Containment and isolation



### LAF and oRABS

- Designed to grant an ISO5 environment
- LED lights
- Standard or polytetrafluoroethylene (= PTFE) filter



### In-line cRABS and Isolator

- Designed to grant an ISO5 environment
- Suitable for operator exposure band - level 5 (= OEB5)
- LED lights
- PTFE filters
- Integrated vaporized H<sub>2</sub>O<sub>2</sub> generator
- 2% or less leak rate
- Compliance with cGMP, GAMP and 21CFR Part11 requirements
- Automatic pressure monitoring and control



### Stand-Alone Isolator

- Designed to grant an ISO5 environment
- Suitable for OEB5
- LED lights
- PTFE filters
- Integrated vaporized H<sub>2</sub>O<sub>2</sub> generator
- 2% or less leak rate
- Compliance with cGMP, GAMP and 21CFR Part11 requirements



## Intelligent compounding system

The intelligent compounding system (= ICS) is a fully automated robotic solution, controlled by software, which compounds parenteral medication doses into the appropriate final containers within a controlled environment (ISO class 4.8, grade A) environment.

The ICS is for use within the compounding practices, both in hospitals and compounding centers, to prepare injections in accordance with appropriate regulations and to label final products in accordance with good practice requirements.

It is based on isolator technology and includes a bio-decontamination system with vaporized H<sub>2</sub>O<sub>2</sub> sterilization technology; it can therefore be installed in an ISO class 8 (grade D) background environment, as per GMP Annex 1.

The ICS can handle both hazardous and non-hazardous medications and both patient specific and batch production.

The ICS includes state of the art automation and robotics to perform the following tasks without requiring human intervention:

- Sterilize all items with vaporized H<sub>2</sub>O<sub>2</sub> prior to starting the compounding cycle
- Calculate conversions between weight and volume on the basis of product and concentration specific gravity data
- Reconstitute powder drugs with the appropriate fluid
- Dilute liquid drugs to achieve a desired concentration
- Remove excess liquid from i.v. bags and bottles
- Compound doses into empty containers(syringes, i.v. bags, elastomeric infusors)
- Manage in-process waste

The ICS addresses safety concerns for users as well as for patients:

- Access restricted to authorized personnel only
- No exposure by using isolator technology
- Automated waste management
- No cross contamination
- Safe identification of all items via a combination of vision systems, barcode readers and RFID technology
- Traceability guaranteed throughout the process via RFID technology





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