Standard range



Key features

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







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





Depyrogenation tunnel, ST

- Energy saving





Filling machine, VFM

Key features

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



External decontamination machine, EDM

- Capacity up to 48,000 pcs/h
- 2R-100H vial range, 1-10 ml ampoules, 1-3













ASEPTIC PROCESSING

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Product overview





chine type	Container	End product	Machine type	Container	End product
ANDARD RANGE			CONTAINMENT AND ISOLATION		
ary washing machine RA-RC	vials - ampoules - cartridges	liquid - lyo - powder	LAF and oRABS	vials - ampoules - cartridges	liquid - lyo - pow
oyrogenation tunnel ST	vials - ampoules - cartridges	liquid - lyo - powder	In-line cRABS and isolator	syringes vials - ampoules - cartridges syringes	liquid - lyo - powo
ing machine VFM	vials - syringes	liquid - lyo			
oping machine VCM	vials	liquid - lyo - powder	Stand-alone isolator	vials - ampoules - cartridges	liquid - lyo - pow
ernal decontamination chine EDM	vials - ampoules - cartridges	liquid - lyo - powder		syringes	
BOTIC RANGE			INTELLIGENT COMPOUNDING SYSTEM		
I filling machine RVFM	vials	liquid - lyo	Intelligent compounding system	syringes - i.v. bags - bottles - elastomeric infusors	liquid
I capping machine RVCM	vials	liquid - lyo - powder			
ernal decontamination chine EDM-RHP	vials	liquid - Iyo - powder			

liquid - lyo - powder

liquid - lyo - powder

Customer service

Tub decontamination system RTDS2 tubs

Include all the activities needed to fix any technical problem in the shortest time possible, from included in the single project or managed independently to satisfy our customers' requirements. registering the request sent by the client to coordinating the different teams to be involved in solving the problem.

Nest filling machine RNFM vials - cartridges - syringes liquid - lyo

Organised training sessions held at the company's HQ in Como, Italy, by our team of experts. Additional follow-up training and information sharing can be completed at the customer's

• Temperature probes

3 Technical audits

Steriline Customer Services can handle requests for technical audits that will be executed • Thermo-couples by experienced mechanical, software and electrical engineers.

4 Software services

New technologies allow the Steriline software team (equipped with the appropriate hardware and software) to remotely access customer machines to diagnose and fix any problem in short

Servomotors

5 Spare parts

- Steriline can offer:
- The fastest components supply service
- •The highest quality material in the market

The possibility of revamping your old Steriline machine/line with the latest technology.

7 Preventive and strategic maintenance

Accurate planning of periodic visits performed by Steriline specialists.

8 Pharma services (on-site qualification/validation) IQ, OQ, PQ and other protocol preparation and execution assistance according to GMP rules.

Steriline engineers support customer learning processes.

Laboratory work

Machine on-board component calibration and setting

With this activity, before the machine's installation, each single component is calibrated and set, providing a turn-key solution that includes:

In addition to our customer service activities, microbiological and analytical works can be either

- Pressure transmitters
- Pressure differential indicators

Machine hardware component calibration and setting

Machine protocol execution support during FATs and on-site: · Process tests (vial cleaning capacity, filling capacity, thermal cycle, air speed uniformity,

- vaporised H₂O₂ decontamination, particle counter integration, etc.)
- Performance testing (machine output, production speed, etc.)



Key features

Capacity up to

2R-100H range

changeover

Quick

36,000 pcs/h

Robotic range





machine, EDM-RHP

Key features

Capacity up to

3,000 pcs/h

2R-500ml range

downtime

Minimum











Designed to deliver an ISO5 environment

- Standard or polytetrafluoroethylene (= PTFE) filter

LED lights

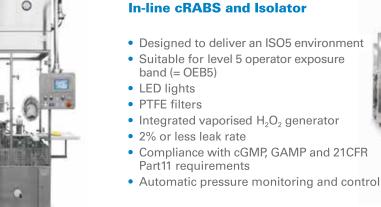






Containment and isolation

In-line cRABS and Isolator



Intelligent compounding system

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

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

It is based on isolator technology and includes a bio-decontamination system with vaporised H_2O_2 sterilisation technology; it can therefore be installed in an ISO class 8 (grade D) background environment, as per GMP Annex 1.

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

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

• Sterilising all items with vaporised H₂O₂ prior to starting the compounding cycle

- Calculating conversions between weight and volume on the basis of product and concentration specific gravity data
- Reconstitution of powder drugs with the appropriate fluid
- Diluting liquid drugs to achieve a desired concentration
- Removing excess liquid from i.v. bags and bottles
- Compounding doses into empty containers (syringes, i.v. bags, elastomeric infusors)
- Management of in-process waste

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

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





Tub decontamination system, RTDS2

Key features

Capacity up to

6,000 pcs/h

◆ 2R-200H range

downtime

Minimum

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



Key features

Capacity up to

2R-100H range

downtime

Minimum

6,000 pcs/h













