

Offer Nr.: 23-13883-1

24-13883_1 SX-100+SX-140-C_OF

Agent
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Biomedical Engineering

"Pharmacy" S.R.L.

Granollers, 13 February 2024

Dear Sirs,

We do appreciate your interest in our table top filling machines for automatic processing of your products. We are pleased to enclose our proposal along with the technical details, as per your specifications:

TABLETOP FILLING AND CLOSURE MACHINES FOR AUTOMATIC PROCESSING OF VIALS
MODEL SX-100 + SX-140-C

Operations:	<p>SX-100 unit.</p> <ul style="list-style-type: none"> - Automatic infeed of vials through a rotary infeed table towards to the pneumatic mechanism to place the vials correctly in the dosing station. - Peristaltic filling system through 1 programmable peristaltic pump model SX-50 Speed fill. - Manual positioning of closures (rubber stoppers/aluminium caps). - Automatic unloading of processed vials onto the output tray. - Movable chassis with wheels made of stainless steel AISI-304. <p>SX-140-C unit.</p> <ul style="list-style-type: none"> - Manual infeed of vials, directly to the star wheel. - Closures previously placed onto the vials. - Manual activation of the process through bi-manual safety buttons. - Pneumatic closing station, through a crimping head. - Movable AISI-304 chassis mounted on wheels // Chassis in AISI-304.
Vial and closures:	<ul style="list-style-type: none"> - Cylindrical glass vial (1 format, no samples) - Aluminium caps (1 format, no samples).

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Product:	<ul style="list-style-type: none"> - Pharmaceutical product (no samples). - Viscosity cps. (to be determined by the customer). - Dose accuracy: $\pm 1\%$. 																																									
Production speed:	<p>For SX-100 Unit:</p> <ul style="list-style-type: none"> - Production speed for 5 ml.: 2.500 – 3.000 up/h <table border="1" data-bbox="389 1033 1453 1302"> <thead> <tr> <th rowspan="2"># Peristaltic pumps</th> <th colspan="6">Filling volumes</th> </tr> <tr> <th>1-5 ml</th> <th>5-15 ml</th> <th>20-30 ml</th> <th>50-60 ml</th> <th>100-125 ml</th> <th>250-300 ml</th> </tr> </thead> <tbody> <tr> <td>1 head</td> <td>50 upm</td> <td>40 upm</td> <td>35 upm</td> <td>25 upm</td> <td>20 upm</td> <td>15 upm</td> </tr> <tr> <td>2 head</td> <td>50 upm</td> <td>50 upm</td> <td>40 upm</td> <td>35 upm</td> <td>25 upm</td> <td>20 upm</td> </tr> <tr> <td>3 head</td> <td>50 upm</td> <td>50 upm</td> <td>45 upm</td> <td>40 upm</td> <td>30 upm</td> <td>25 upm</td> </tr> <tr> <td>4 head</td> <td>50 upm</td> <td>50 upm</td> <td>50 upm</td> <td>45 upm</td> <td>35 upm</td> <td>30 upm</td> </tr> </tbody> </table> <p>Estimated speed on water product (H₂O). For your product, the speed depends on the number of nozzles, dosing volumes, characteristics of the product (foamy, viscosity, density, etc.).</p> <p>For SX-140-C Unit:</p> <ul style="list-style-type: none"> - Production speed: 1.300 – 1.500 up/h <p>SPEEDS SUBJECT TO BE TESTED ON CUSTOMER'S PRODUCT.</p>	# Peristaltic pumps	Filling volumes						1-5 ml	5-15 ml	20-30 ml	50-60 ml	100-125 ml	250-300 ml	1 head	50 upm	40 upm	35 upm	25 upm	20 upm	15 upm	2 head	50 upm	50 upm	40 upm	35 upm	25 upm	20 upm	3 head	50 upm	50 upm	45 upm	40 upm	30 upm	25 upm	4 head	50 upm	50 upm	50 upm	45 upm	35 upm	30 upm
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Pict. 1. General view of model SX-100. This illustration may vary from the offered equipment.

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Pict. 2. General view of model SX-140-C. Final configuration may differ.

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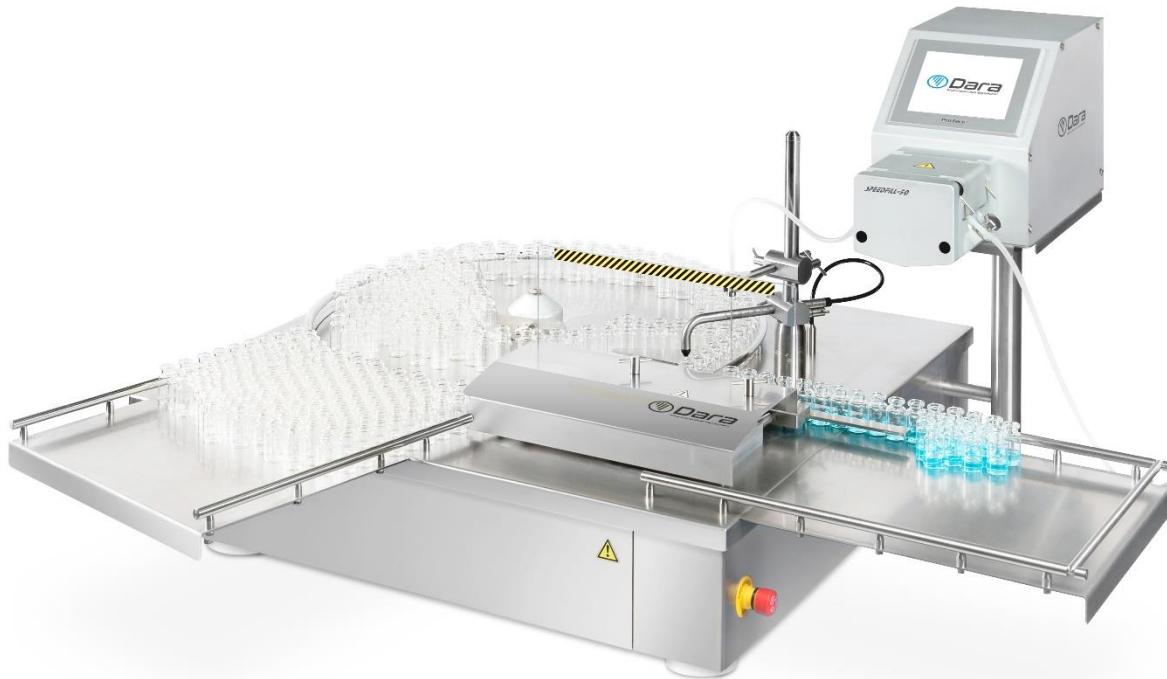
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1. MODEL: SX-100: FILLING MACHINE FOR AUTOMATIC PROCESSING OF VIALS AND BOTTLES

1.1 GENERAL DESCRIPTION OF THE EQUIPMENT

- Machine chassis and tray made of stainless steel AISI-304.
- Supports and columns made of stainless steel AISI-304 and anodized aluminium.
- The design and surface finish of all parts allows easy cleaning and care.
- Variable working speed through touch screen placed in the chassis of the machine.
- Acoustic level: L eq < 70 dB (A).
- **Maximum vial Ø = 68 mm.**
- Maximum vial height = 210mm.



Pict. 3. General view of model SX-100. This illustration may vary from the offered equipment.



Pict. 4. General view of model SX-100. This illustration may vary from the offered equipment.

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1.2 FILLING SYSTEM

1.2.1 Tabletop Peristaltic Dosing Pump, model SX-50 *SpeedFill*

- Aseptic filling with no cross contamination.
- Filling from 0.5 ÷ 500 ml.
- Dosing Accuracy +- 1% => Single Head Peristaltic Pump accuracy of +- 1% (Note: Accuracy of multiple Head Pumps, accuracy could vary).
- Flow up to 6,4 L/min.
- Conforms with GMP-US FDA.
- Filling volume and anti-drop function can be programmed from the control panel.
- Different configurations of dosing, dose volume, dose speed, etc. can be saved from the control panel.
- Estimated time for sanitization of the machine is 5 minutes and it doesn't require tools.
- Standard power and control electronics.

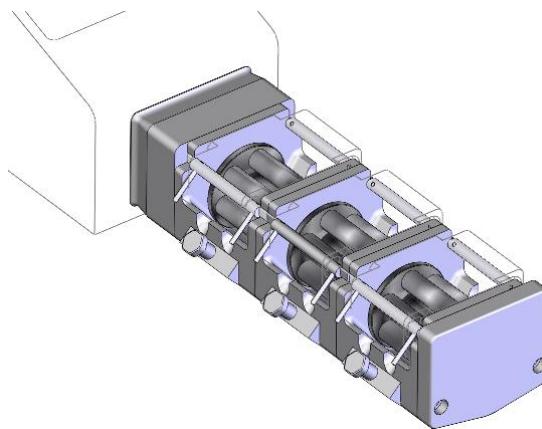


Pict. 5. General view of model SX-50. This illustration may vary from the offered equipment.

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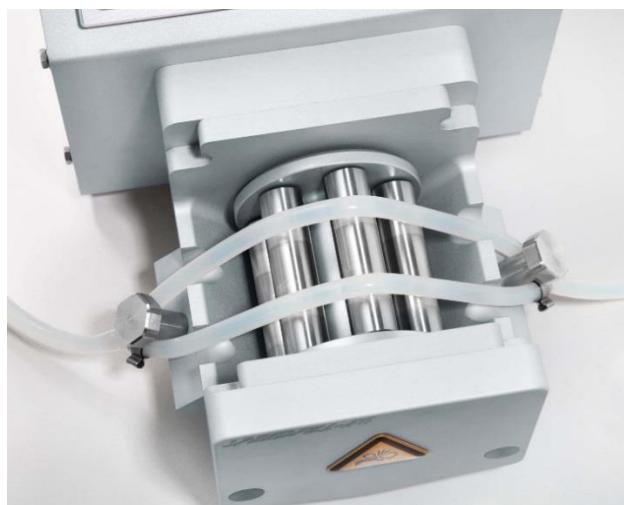
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- Peristaltic filling has become, in a short time, the favourite system for pharmaceutical industry. It offers sterility, flexibility and it is easily cleaned, thanks to the fact that the fluid is in contact only with the inside of the tube and the dosing needle.
- It has been designed for its use in sterile area and it complies with cGMP and US-FDA regulations, in special compliance with the requirements of the pharmaceutical industry.
- SX-50 is propelled through a powerful servomotor, capable of accepting up to 3 heads in series. The body of the head is a Monobloc, built in one piece for better asepsis.



Pict. 6. Detail of the rollers inside the pump. This illustration may vary from the offered equipment.

- The peristaltic head pumps the fluids in a smooth and progressive way, without closing its molecular chain. It is excellent for the dosing of suspended solids, vaccines, cellular tissue and other sensitive fluids.
- The equipment is built with the best standard components in the market. Therefore, elements such as servomotor, reducer, touch screen or control PLC are easy to replace in any geographical area, which makes its maintenance simple and fast.



Pict. 7. Detail of the rollers inside the pump. This illustration may vary from the offered equipment.

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- “Platinum Cured Silicone” tubes are manufactured in an aseptic room and they are easy to sterilize through autoclave or through gamma rays’ radiation.
- Range of tubes: Ø Int.: 0,5 / 0,8 / 1,6 / 3,2 / 4,8 / 6,4 / 8 / 9,6 mm. Tube thickness: 2,4 mm.
- Tubing is not included in the final price.
- Recommendable Watson Marlow standards tubing.
- All production parameters are stored in the system memory and parameters such as:
 - Dosing volume.
 - Kinematics of the filling process, individual control of acceleration and deceleration ramp.
 - Interval of time between dosing.
 - Calibration parameters.
 - “Drip-free” function.
 - Production speed.
- They are automatically regulated and associated to each dosing program. The machine can store up to 200 programs of different production batches.
- The design of the machine allows it to work independently or to be part of an industrial filling machine, fully automatic.

1.3 SECURITY AND ELECTRICAL BOX

- Ingress protection: IP-31.
- Voltage 120-230v – 50/60Hz
- CE mark.
- Design and construction of the machine as per GMP Standards.
- Technical documentation included:
 - Technical dossier of installation, operation and maintenance in English.
 - Electrical diagrams in 2 copies.



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2. MODEL SX-140-C: TABLETOP MACHINE FOR AUTOMATIC CLOSING OF CONTAINERS

2.1 GENERAL DESCRIPTION OF THE EQUIPMENT

- Machine frame and tray made of AISI-304 Stainless Steel.
- Supports and columns made of AISI-304 Stainless Steel and anodized duraluminum.
- The design and surface finish of all parts allow easy cleaning and care.
- Working speed is variable through pneumatic activation.
- Acoustic level: L eq < 80 dB (A).
- Circular motion, through 1 set of star wheels for 1 format of container, made of POM.
- Changeover to a different format is easy and quick and does not require tools.



Pict. 8. General view of SX-140-C. Final configuration may differ.

2.2 PNEUMATIC CLOSING STATION

- Closing station for alu caps through a pneumatic crimping head.
- Minimum generation of particles during the closing process.
- Pneumatic vertical haul of the closing station.
- Festo pneumatics, 6 bar clean air pressure is required.
- Activation of the mechanism through bi-manual safety buttons.



2.3 SECURITY AND ELECTRICAL BOX

- Ingress protection: IP-31.
- Voltage 120-230v – 50/60Hz
- CE mark.
- Design and construction of the machine as per GMP Standards.
- Technical documentation included:
 - Technical dossier of installation, operation and maintenance in English.
 - Electrical diagrams in 2 copies.

3. SERVICES

3.1 IQ / OQ (INSTALLATION QUALIFICATION/OPERATIONAL QUALIFICATION) DOCUMENTATION

- This section describes the IQ / OQ qualification documentation of the machines:



Pict. 9. Validation Documentation.

- **Installation Qualification (IQ)** this is the documented evidence that the machine has been installed according to the User Requirements (URS) and/or the Design Specifications defined in the offer/order. These tests are carried out without running the machine.
- This qualification stage should be done at the customer's facilities (the IQ execution is not included in this section; it must be required separately. This part only includes the protocol delivery).
- This is an indicative list of the tests included in this qualification stage (IQ) are¹:

Documentation Verification Test (As Built)
Conformity of drawings (As Built)
Conformity of components
Materials certification according to ASME/BPE 2.1
Touch Screen installation verification.
PLC Installation verification
Utilities verification test

¹ Note: This list is not to be considered as binding. If any of the items listed are not quoted, the test will not be carried out.

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- **Operational Qualification (OQ)** this is the documented evidence that operation of the machine complies with the User Requirements (URS) and/or the Design Specifications defined in the offer/order.
- This qualification stage should be done at the customer's facilities (the OQ execution is not included in this section, it must be required separately. This part only includes the protocol delivery).
- This is an indicative list of the tests included in this qualification stage (OQ) are²:

Verification of start-up and shutdown of the equipment
Safety Systems and function verification
Access levels test
Alarms and interlocks
Screens verification
Recipes Management
Operational test for each format
Dosing capacity test (<i>Only filling machines</i>)
Washing capacity test (<i>Only washing machines</i>)
Filter integrity test (<i>Only depyrogenation tunnels and laminar flow devices</i>)
Air speed test (<i>Only depyrogenation tunnels and laminar flow devices</i>)
Particle counting test – “at rest” and “at work” (<i>Only depyrogenation tunnels and laminar flow devices</i>)
Temperature homogeneity (<i>Only depyrogenation tunnels</i>)
Depyrogenation and cooling test for each format (<i>Only depyrogenation tunnels</i>)
Smoke test (Air Flow Patterns) (<i>Only for laminar flow devices</i>)

- **The IQ/OQ execution by DARA specialized personnel has to be ordered separately (it is not included in this validation package).** If selected, tests performed during FAT related to parts of the equipment that do not suffer any modification during Transport and Installation, will be leveraged and traced to the FAT documents.

² Note: This list is not to be considered as binding. If any of the items listed are not quoted, the test will not be carried out.

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3.1 MATERIALS CERTIFICATION 3.1

- This certification complies the normative **UNE-EN 10204:2006** and includes these documents:

REQ. #	Materials Requirements
1M	Materials certification with traceability of each piece respect to the certificate. (Traceability 100%)
3M	Metallic materials in direct contact with the product: Stainless steel AISI316L with maximum rugosity $Ra < 0,6 \mu\text{m}$. The certification includes: id piece, material type and max. rugosity.
5M	Elastomers (joints, membranes, hoses, suction cups ...): FDA compliant materials suitable for use in the pharmaceutical industry (Silicone, EPDM, Viton, PTFE, ...)
6M	Rigid plastics: POM C, PEEK

REQ. #	Welding Requirements
1W	Welding traceability 100%
2W	TIG orbital welding without material contribution, purged with Argon of minimum purity 99.995%.
3W	Welding process specification
4W	Welding process Qualification
5W	Welding Machine Certification Certificate
6W	Welder qualification certificate
7W	Radiographs 10% welds with radiographic test report
8W	Passivation certificate (you must ensure that the surfaces are passivated, in particular those affected by cuts, welds, ...).
9W	Boroscopy 100% manual welding with results report