




Filling and Closing Machines

Vials and Infusion Bottles for Liquid and Powder

OPTIMA

EXCELLENCE IN PHARMA

Member of

PACKAGING VALLEY Germany



OPTIMA pharma –
Leading in Quality and Diversity

Optima Pharma excels in meeting the pharmaceutical industry's highest expectations with the four brands Inova, Kugler, Klee and Metall + Plastic. Optima Pharma offers a diversified and innovative portfolio of filling and packaging machines for sterile and non-sterile pharmaceutical liquids and powders in addition to supplying lyophilization and isolation technology.

Optima Pharma is internationally recognized by the pharmaceutical industry for machine efficiency and precise realization of complex turnkey projects.





Contents

04 Washer

06 Sterilization Tunnel

08 Filling and Closing Machines

16 Loading and Freeze Drying

18 Closing Machines

20 Tray Loader

22 Clean Production

24 Line Concept Integration

30 Service

31 Contact us

Washer

The Perfect Solution for Wet Cleaning

Optima Pharma washers are completeley made of stainless steel, non-corrosive, pharma-conform plastics. The washers are designed in accordance with cGMP standards and have a wide variety of usage. Product contact parts are easy to clean and designed to facilitate accessibility. For the cleaning and treatment of containers, all cleaning media customary to the pharmaceutical industry can be used.

Two different designs are available:

- ▶ Tunnel Washers
- ▶ Rotary Washers



Tunnel Washer

Fully-automatic tunnel washers are designed for automatic and continuous cleaning of vials and infusion bottles. Washers are available with or without ultra-sonic pre-treatment and the connection to a sterilization tunnel can be performed with ease. Output up to 30,000 containers/hour with extremely gentle treatment of your containers.

Rotary Washer

Fully-automatic rotary washers for the treatment of vials and infusion bottles. Washers are available with or without ultra-sonic pre-treatment and the connection to a sterilization tunnel can be performed with ease. Output up to 24,000 containers/hour. The transport can be either cycled or continuous by means of one or several laned transport grippers.



Washer

Tunnel Washer

Technical Data:			
Type	**12**	**17**	**18**
Machine type	Fully-automatic		
Containers	Vials and infusion bottles		
Container size range: Neck opening Outer diameter Max. height	> 7 mm 20 – 52 mm up to 104 mm	> 7 mm 14 – 32 mm up to 75 mm	> 13 mm 22–86 mm up to 180 mm
Spray positions	9 – 20	10 – 25	10
Output (depending on container shape size)	up to 24,000 containers/h	up to 30,000 containers/h	up to 12,000 containers/h
Cleaning sequences	10		
Spray duration per station	1.9″ – 7.5″	1.8″ – 7.2″	1.9″ – 12″
Max. number of recirculation pumps	2		
Infeed of containers	Carrier pockets		

Rotary Washer

Technical Data:				
Type	**VWM 218**	**WMR 600**	**WMR 1800**	**WMR 2400**
Machine type	Fully automatic intermittent	Fully automatic continuous		
Containers	Vials and infusion bottles			
Container size range: Neck opening Outer diameter Max. height (depending on container shape)	> 7 mm 16-80 mm up to 180 mm	> 5 mm 7-52 mm up to 105 mm	> 5 mm 7-52 mm up to 105 mm	> 5 mm 7-42 mm up to 105 mm
Spray position	1– 3	1-4	1-6	1-8
Output (depending on container shape and size)	up to 7,200 containers/h	up to 12,000 containers/h	up to 18,000 containers/h	up to 24,000 containers/h
Processing sequences	8	7	6	
Ultrasonic infeed/Siliconization	-	optional		
Max. number of recirculation stations	1			
Infeed of containers	Transport grippers			

Sterilization Tunnel

For all Purposes

Optima Pharma sterilization tunnels are part of a complete aseptic filling line designed to sterilize and to depyrogenate glass containers such as injection and infusion bottles and syringes – from cleaning to aseptic filling a continuous operation mode in a clean room environment. The tunnel program consists of Laminar-Flow (LF) hot air tunnels, and infrared/hot air combination tunnels. Depending on your application, Optima Pharma has the right tunnel for you.



The cleaned containers are transported through the infeed, which is equipped with Laminar Flow, into the sterilization area – the heating zone. The containers are heated to a defined temperature in order to ensure secure sterilization and depyrogenization. Sterilization can be performed by means of LF-hot air, or a combination of hot air and infrared quartz glass heaters. Both of the sterile systems are designed for defined applications. The tunnels are equipped with state-of-the-art automation and communication systems. This ensures detailed data recording and tracing of temperatures.



Sterilization Tunnel



Sterilization Tunnel

Technical Data:	
Type	**SHT/SHT IR**
Conveyor belt width	300, 450, 600, 800, 1250, 1600
Transport height	900 mm +/- 25 mm
Filter system	HEPA filters - H13/H14
Output	up to 44,000/h. bei 10H (depending on container)
Heating temperature output	20 – 200 KW (depending on output)
Cooling power	0.3 – 15 m³/h
Sterilizable cooling zone	Optional

Heat sterilization of the cooling zone

- Automatically lockable and heated gas-tight tunnel door with sealing at the outfeed ot the tunnel
- Isolation of the cooling zone
- Special fans
- Separate closed cooling circuit with recirculation pump and mixing valve for the sterilizable cooling zone
- Sterilization program for sterilization implementing



Filling and Closing Machines

Stand Alone and Complete Turn-Key Lines

Modular and compact designed machines according to cGMP standards with minimum space requirement – the fully-automatic Optima Pharma filling and closing machines are used for a wide range of applications, are designed for your individual needs and can be easily retrofitted.





Filling and Closing Machines

Compact Line VFVM 221/231

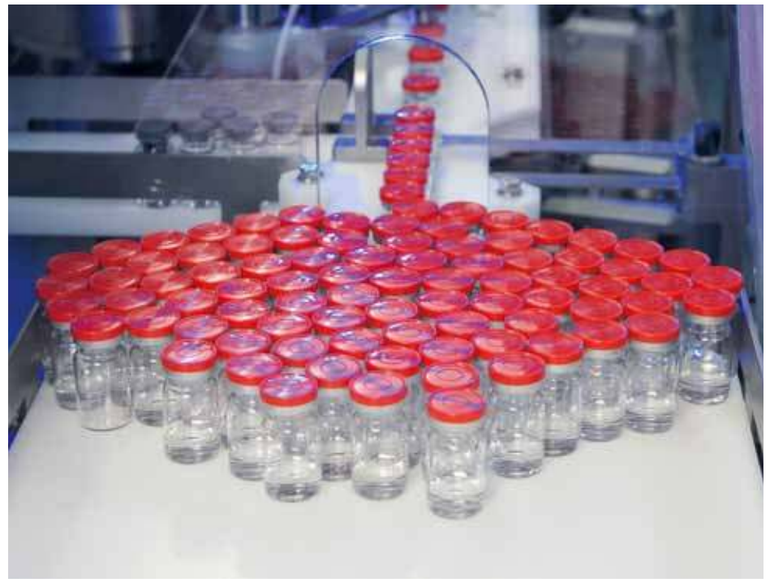
In laboratories and R&D the demands on technical equipment for the manufacture of sterile and aseptic products are continuously increasing.

Optima Pharma has a leading position in the field of sterile filling technology. To meet the market challenges a custom-made integral solution for the processing steps of:

- ▶ Washing
- ▶ Sterilizing
- ▶ Filling
- ▶ Stopper insertion
- ▶ Crimping (optional)

has been developed.

This state-of-the art compact concept meets all known requirements regarding technological design and the ever increasing cGMP regulations. The filling machine is also available as a stand-alone model.







Filling and Closing Machines

Large Range, Compact Design

Type VFVM 3000/4000

A fully-automatic filling and closing machine for vials and infusion bottles. Compact designed machines according to cGMP standards – machines are used for a wide range of applications and designed for your individual needs and can be easily retrofitted.



Filling and Closing Machines



Filling and Closing Machines

Flexibility by Means of a Modular Design

Type VFVM
7000 / 10000 / 18000 / 2400

A fully automatic filling and closing machine to process vials and infusion bottles from 0.1 ml to 500 ml. Output 500 - 27,000 objects/h. depending on product viscosity and fill volume.

Advantages of the rake transport system versus the alternative system for machines with a medium output: The vials and infusion bottles are not processed or filled in a star wheel or on a conveyor belt. Easy access to the individual station due to the narrow design of the machine. The vials/infusion bottles are continuously secured and centered during transport ensuring that the vials or infusion bottles will not topple over or interchange. The linear transport system permits better accessibility for cleaning and monitoring of processes. The absence of a transport star wheel allows for faster and safer change of size parts.





Filling and Closing Machines

Our Dosing Systems At a Glance

In order to decide on the most suitable filling system for sterile pharmaceutical liquids and powders, different factors must be taken into consideration:

- The diverse product characteristics
- Environmental conditions of the filling process
- Given format diversities
- The specified output
- The specified dosing accuracy

The following systems are considered:

Time Pressure



Time pressure dosing system is the most frequently installed in pharmaceutical applications.

Peristaltic Pumps



Peristaltic pumps enjoy a high preference in biotechnological applications.

Disposable Systems



Disposable systems mark the future trend in the world of drug manufacturing and play a huge role in the development of new processes and products.

Rotary Piston Pumps



Self-sucking rotary piston pumps are applied for a wide range of products.

Mass Flow Meter



Mass flow meter is usually installed in applications where product viscosity is temperature-sensitive.

Powder dosing



Auger filling for sterile filling of powders.

Filling and Closing

Sterile Liquid and Powder

Optima Pharma is one of the world's leading organization for pharmaceutical filling, packaging and freeze drying technologies but also houses a team of skilled integrators ranging from designers, project engineers to the most qualified technicians and programmers.
This in-house expertise and know-how allows Optima Pharma to act as a one-stop-shop where customers benefit from sourcing a wide range of solutions from a single provider.

Why OPTIMA pharma?

- Leading position in sterile, aseptic filling, freeze drying and clean room technology
- Custom-tailored solutions for even the most complex projects
- One-stop-shop
- State-of-the-art GMP compliant machines
- Reliable, goal-orientied, efficient, innovative and flexible
- Comprehensive service packages





Technical Data:

Type	VFVM 2000	VFVM 3000	VFVM 4000	VFVM 7000 VFVM 10000	VFVM 18000	VFVM 24000
Machine description	Compact laboratory machine (Stand alone model or in line integration)	Fully automatic filling and closing machine				
Containers	Vials	Vials and infusion bottles	Vials and infusion bottles			
Infeed	Manual onto turn table From sterilization tunnel onto turn table	Conveyor belt, Transport scroll, Turn table	Conveyor belt Turn table	Conveyor belt Turn table	Conveyor belt Turn table	Conveyor belt Turn table
Filling volume	0.1–100 ml	0.1–250 ml	0.2–250 ml	0.1–15 ml (4-lane) 0.1 - 100 ml (2-lane) 0.1 - 500 ml (1-lane)	0.1–500 ml	0.1– 100 ml
Container size range	1-lane: Ø 14 –52 mm Height: max. 110 mm	1-lane: Ø 16 –66 mm (36 mm 2-lane) with infeed scroll: Ø max. 30 mm Height: max. 75 mm	Round containers: up to Ø 100 mm Height: max. 220 mm	Transport star wheel, Ø max. 24 mm (4-lane) Ø max. 52 mm (2-lane) Ø max. 86 mm (1-lane)	2R–500 IL	Ø 14.5–52 mm Height: 30–105 mm
Output (Containers/h.)	up to 45 containers/min.	up to 4,200 (up to 7,000 2-lane)	up to 4,200 (up to 7,000 2-lane)	up to 7,200 2-lane up to 12,000 4-lane	up to 24,000	up to 30,000
Operators	1					
IPC	100 %	statistical	statistical	100 %	100 %	statistical

Loading and Freeze Drying

Sophisticated Perfect Solutions

The manufacturing as well as the handling of pharmaceutical products not only requires a high degree of competence by all parties, but also meticulous handling of the products.

In 2005, Klee GmbH joined Optima. Thanks to many years of specialization, as a brand of Optima Pharma, Klee offers a comprehensive and technically leading product range:

- Sterilizable freeze drying plants for the pharmaceutical industry – from high-tech pilot plants to highly efficient production plants. A seamless scaled version of the pilot plant to a full size production plant is guaranteed.
- Fully automatic loading and unloading systems for vials, ampoules, syringes or bulk loading; also in connection with RABS or isolator technology.
- Upgrades of machines not fulfilling state-of-the-art technology or those who are no longer up to date with the current regulations.
- Consulting, training, service, and maintenance.







Loading and Freeze Drying

Greater benefits for the user

Highlights Freeze Drying

- Flexible and customer focused layout concepts
- Shelves which display an extremely even temperature distribution
- Fully automatic filter test units (WIT)
- Steam sterilization at 1.5 bar
- H_2O_2 sterilization
- Clean In Place (CIP) with a cleaning process that can be validated
- Visualization with Klee Lyomatic and standard applications
- Modem support /remote control
- Processing of solvents in compliance with ATEX directive

Highlights Loading and Unloading Systems

- Innovative solutions tailored to the customer's requirements, e.g. a loading cart freely mobile in a room
- Loading row by row, shelf by shelf, frame by frame
- Fully automatic handling of vials, ampoules, syringes and magazines
- Isolator or RABS technology



Closing Machines

Fine Tuned for your Product and Containers

Machines designed to close a wide variety of containers for the pharmaceutical industry. Even in the basic machine, several design details are utilized, which sets us apart from the standard:

- Electronic and central height adjustment
- Selectable torque function
- PLC guided size part change



The following process steps are possible:

- Stopper insertion
- Crimping
- Screwing
- Insertion of droppers, spray pumps and pipettes
- Placing of press-on caps



Closing Machines



Technical Data:

Type	VVM 211	VVM 3000	VVM 4000	VVM 7000	VVM 2400
Machine description	Fully automatic closing machine				
Containers	Vials and infusion bottles				
Infeed	Turn table with feeding plate	Conveyor belt, Transport scroll, Turn table	Conveyor belt, Turn table	Table rotative	Table rotative
Container size range	Ø 15 – 52 mm Height: 30 up to 105 mm	Ø 15 – 66 mm Height: 30 up to 140 mm	Ø 15 – 100 mm Height: 30 up to 200 mm 1-lane	Ø 40 – 86 mm Height: 68 – 147 mm 1-lane Ø 15 – 52 mm Height: 35 – 105 mm 2-lane	Ø 15 – 52 mm Height: 35 up to 105 mm (10-lane) Ø 40 – 86 mm Height: 68 up to 147 mm (8-lane)
Output (containers/h)	45/min 1-lane	up to 4,200 1-lane (up to 7,000 2-lane)	up to 4,200 1-lane up to 7,000 2-lane	up to 3,600 1-lane up to 7,200 2-lane	up to 14,000 8-lane up to 27,000 10-lane
Operators	1				
Space requirements	0,7 m²	0,8 m² (without convey or belt, sorting and feeding devices)	1,4 m² (without convey or belt, sorting and feeding devices)	1,4 m² (without convey or belt, sorting and feeding devices)	1,6 m² (without convey or belt) sorting and feeding devices are integrated

Tray Loader

Supplementary Machines to Handle Vials

An exact number of steady vials or bottles can be loaded with our fully automatic, high speed tray loader. Two/four trays are filled alternately, ensuring tray swapping without machine stop. By means of a conveyor belt equipped with a minimum accumulation sensor, the vials/bottles are fed into the infeed. Reciprocal interlocks at the infeed create an accumulation with the exact number of vials/bottles. The accumulated vials/bottles are transported in front of the pusher, with a stopping finger ensuring the correct placement of the vials/bottles. To prevent the vials/bottles from tipping over, a mechanically driven pusher with a counter guide maintains their placement. The number of cross pushers are counted, to ensure the exact equal amount of vials/bottles in each tray. The trays are secured against overload.



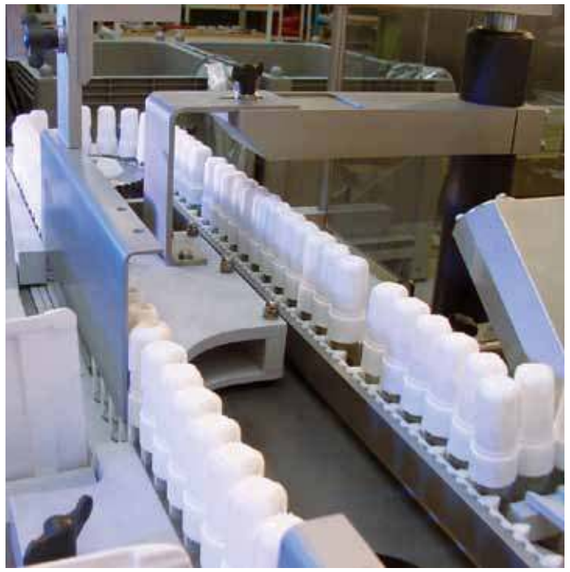
Advantages

The machine works according to the FIFO principle (First in – First out). During the process no vials remain on the conveyor belt.



Tray Loader





Technical Data:

Type	M 2412	M 2424
Machine Description	Fully-automatic Tray Loader	
Number of trays	2	4
Containers	Steady vials and bottles Diameter: 14.5 up to 78 mm Height: 30 bis 240 mm	
Traying possibilities of vials/bottles	Width: 250 up to 500 mm Length: 300 up to 600 mm	Width: 250 up to 400 mm Length: 300 up to 600 mm
Traying possibilities	No nesting Semi nesting Full nesting	
Output (depending on container diameter and tray configuration)	Max. 12,000 pcs./h	Max. 24,000 pcs/h

Clean Production
Triple Protection

Clean room technology provides the basis to ensure a safe production environment for filling sterile drugs.

The filling technology provides for the precise dosing of drug products under the aspect of sterile product handling. Optima Pharma unites the required clean room technology with the state-of-the-art filling technology to help you market a high-value pharmaceutical product. The portfolio of Optima Pharma and the brands Inova and Metall + Plastic offer three different technical air protection systems:

- Restricted Access Barrier System (RABS)
- Closed Restricted Access Barrier System (C-RABS)
- Isolator





At first glance, all three systems work as a clean room micro plant. But as far as technology and regulation are concerned, the differences are quite considerable and have to be assessed for each individual project. We would be happy to recommend the correct protection system suitable for your application.

Restricted Access Barrier System (RABS)



To restrict the operator access to the process area, our filling machines can be provided with RABS equipment as an option. The restricted access is in this case achieved by glove systems, and mock-up studies are used to determine in advance the gloves' positions.

Ventilation concept
The required process air is taken from the machine environment and filtered by means of a HEPA filter. Variable speed-controlled ventilators supply constant air volume to the unit. Air distribution is achieved by means of a plastic diaphragm, which ensures uniform air distribution in the protected area with little turbulence.

Closed Restricted Access Barrier System (C-RABS)



System description / technical module
The technical module consists of high-quality stainless steel materials and is located above the protection module. It contains the complete technical air equipment, such as ventilators, filters, cleanroom illumination and air distribution diaphragm.

Protection module
The protection module consists of high-quality stainless steel materials. Doors, windows and other functional elements are integrated into the modular sectional framework, as required for the individual machine. Intervention in the protection module is achieved by means of glove accesses that are integrated into the glass doors (tempered safety glass (ESG)).

Isolator



Possible operation parameters
- Air speed
- Pressure regulation (option)
- Air temperature (option)
- Humidity

Turnkey Line Solutions

INOVA WM 12, SHT 12, VFVM 18000, VVM 2428 with outside washer,
KLEE Freeze dryer, M+P Isolator

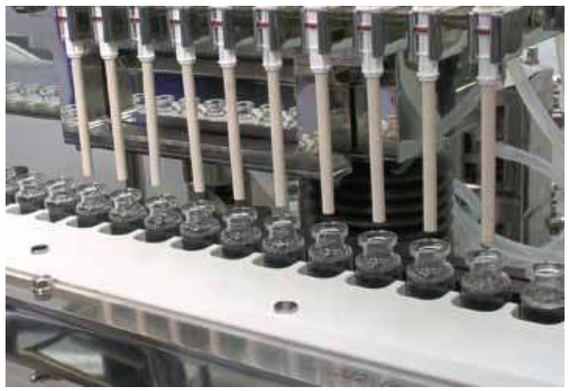
Vial Ø
24 mm

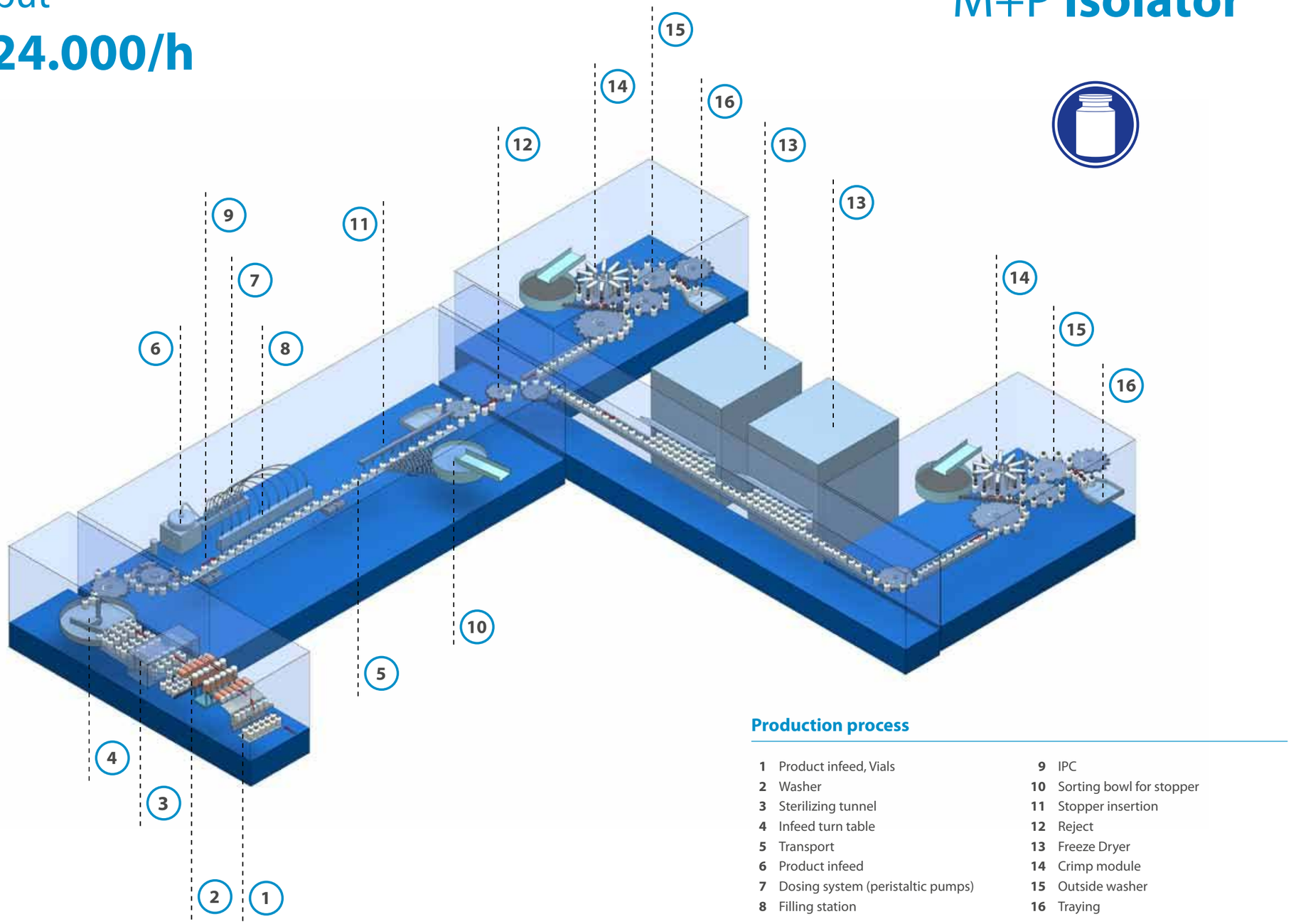
Output
up to **24.000/h**

M+P **Isolator**

Features

- Cold loading via nitrogen curtain
- Empty vial inspection
- 5 double stacked peristaltic pumps
- Oxygen less than 1%
- Processing of toxic products





Production process

1	Product infeed, Vials	**9**	IPC
2	Washer	**10**	Sorting bowl for stopper
3	Sterilizing tunnel	**11**	Stopper insertion
4	Infeed turn table	**12**	Reject
5	Transport	**13**	Freeze Dryer
6	Product infeed	**14**	Crimp module
7	Dosing system (peristaltic pumps)	**15**	Outside washer
8	Filling station	**16**	Traying

Container size range

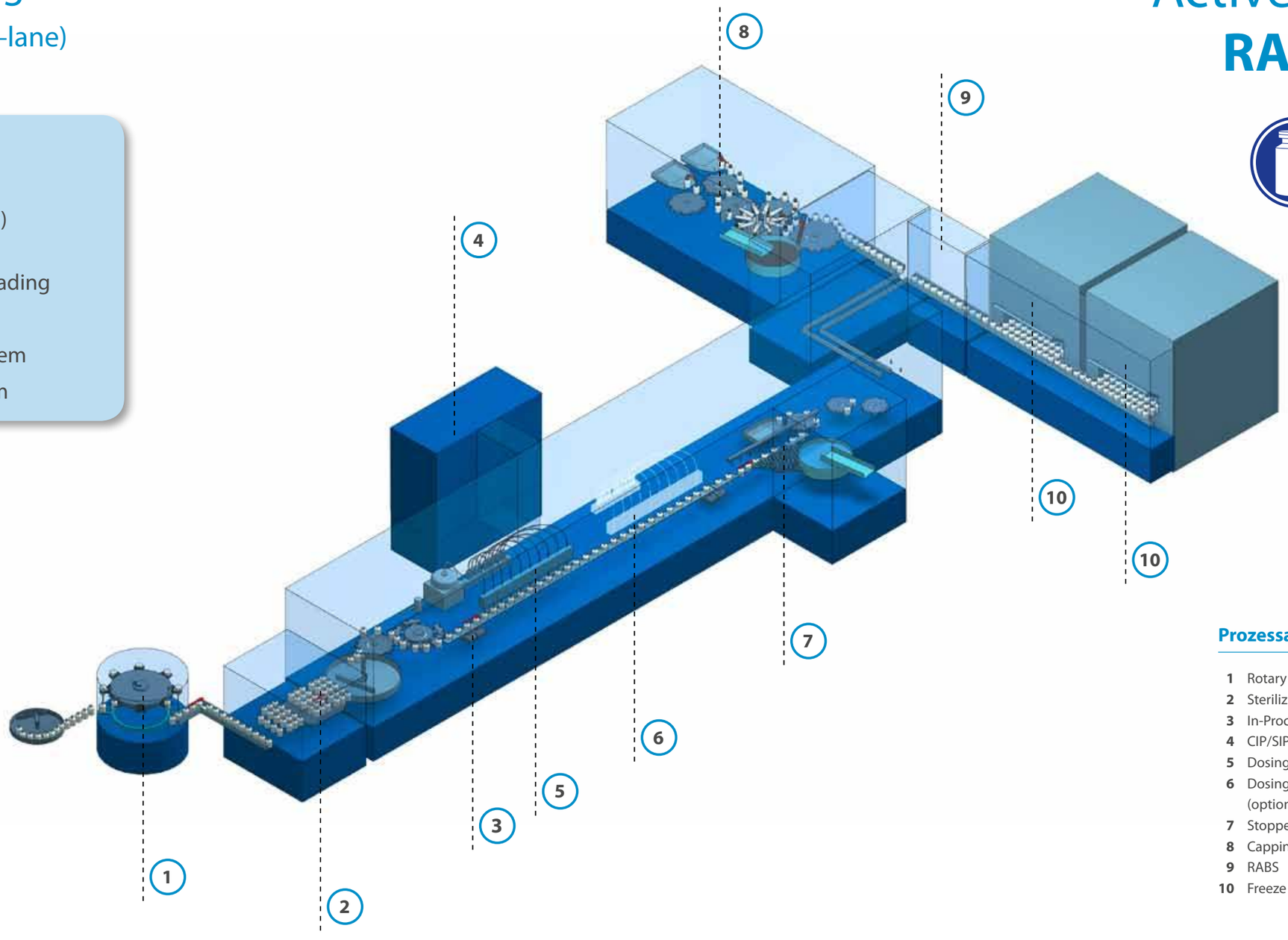
2R–25R (up to 10–lane)

Features

- Two Dosing systems:
  - Peristaltic pumps (CIP / SIP)
  - Time pressure (CIP / SIP))
- Fully automatic row by row loading and unloading
- Glass particle monitoring system
- Cap quality monitoring system



Active open **RABS**



Prozessablauf

1. Rotary washer
2. Sterilizing tunnel
3. In-Process Control
4. CIP/SIP Cabinet
5. Dosing module: Time pressure
6. Dosing module: Peristaltic pumps (optional)
7. Stoppering module
8. Capping machine
9. RABS
10. Freeze dryer, RALUT

Processing Line for Vials under Isolator

INOVA WMR 600, SHT 19 S, VFVVM 7042, EVK 7000

Output
up to **5,400/h**

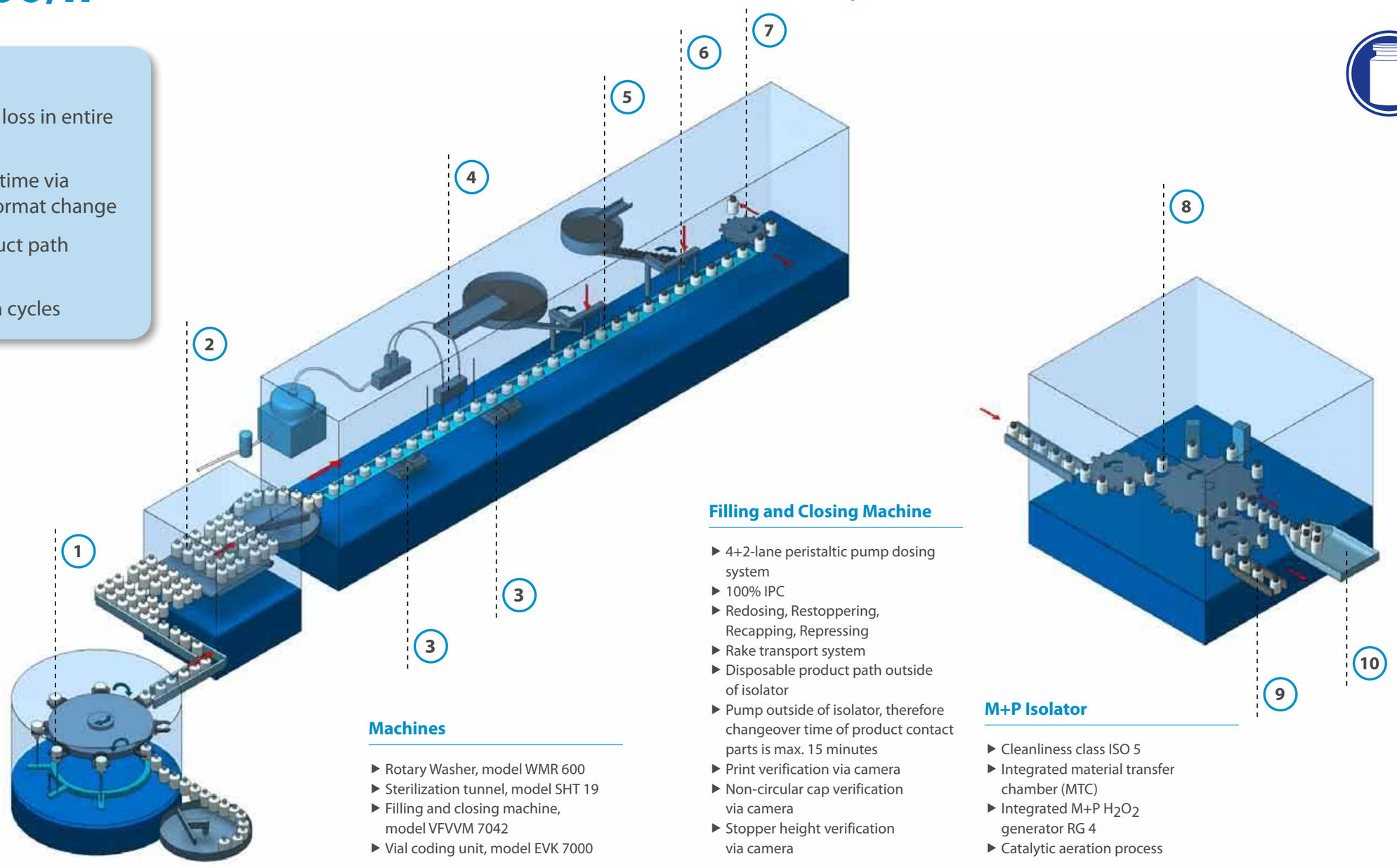
Vial
10–500 ml

Minimized
product loss

100 %
In-Process Control

Features

- Minimal product loss in entire batch process
- Fast changeover time via fully automatic format change
- Disposable product path
- Reduced VHP decontamination cycles



Prozessablauf

1 Rotary washer
2 Sterilizing tunnel
3 In-Process Control
4 Dosing module
5 Stoppering station
6 Capping module
7 Reject
8 Vial coding unit
9 Reject
10 Traying

Machines

- Rotary Washer, model WMR 600
- Sterilization tunnel, model SHT 19
- Filling and closing machine, model VFVVM 7042
- Vial coding unit, model EVK 7000

Filling and Closing Machine

- 4+2-lane peristaltic pump dosing system
- 100% IPC
- Redosing, Restoppering, Recapping, Repressing
- Rake transport system
- Disposable product path outside of isolator
- Pump outside of isolator, therefore changeover time of product contact parts is max. 15 minutes
- Print verification via camera
- Non-circular cap verification via camera
- Stopper height verification via camera

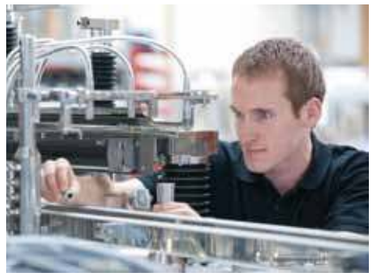
M+P Isolator

- Cleanliness class ISO 5
- Integrated material transfer chamber (MTC)
- Integrated M+P H_2O_2 generator RG 4
- Catalytic aeration process

Service

A Comprehensive Service Program

Process reliability is also a question of service. Even the best machines and lines are subject to a certain extent of wear. With our team of experts and the worldwide available service network of the Optima Pharma, you will reduce the risk of machine downtime to a minimum. Additionally, a 24-hour hotline as well as an extensive spare parts supply within a very short time are at your disposal. Electronic spare parts catalogs, comprehensive technical documentation and operating instructions as well as the teleservice, facilitate the competent handling of trouble-shooting. Service already starts when commissioning the machine. The Optima Pharma offers you training specifically adapted to your requirements. Incidentally, itis not always necessary to invest in new machinery.



Innovative machine upgrades and individual retrofitting packages of the Optima Pharma upgrade your machines to the state-of-the-art. Ask us for a service package meeting your requirements. It will be our pleasure to assist you.



Contact Us

The Safety of a Strong Partner



OPTIMA pharma GmbH
Otto-Hahn-Str. 1
74523 Schwäbisch Hall
Tel.: +49 791 9495-0
Fax: +49 791 9495-2610
info@optima-pharma.com
www.optima-pharma.com

OPTIMA pharma GmbH
Vor dem Langen Loh 8
35075 Gladenbach-Mornshausen
Tel.: +49 6462 91576-0
Fax: +49 6462 91576-148
info@optima-pharma.com
www.optima-pharma.com

METALL + PLASTIC GmbH
Bodmaner Str. 2
78315 Radolfzell-Stahringen
Tel.: +49 7738 9280-0
Fax: +49 7738 9280-10
info@metall-plastic.de
www.metall-plastic.de

OPTIMA Packaging Machinery PLC
7 Loader Close
Kings Worthy
Hampshire SO23 7TF, Great Britain
Tel.: +44 1962 620898
Fax: +49 791 506 6500
info@optima-gb.com
www.optima-gb.com

OPTIMA Packaging France S.A.R.L.
Zone d´Activités de l´Energie
4, rue Ampère B. P. 9
59559 Comines Cedex, France
Tel.: +33 320 6306-48
Fax: +33 320 6306-41
info@optima-fra.com
www.optima-fra.com

OPTIMA Machinery Corporation
1330 Contract Drive
Green Bay, WI 54304, USA
Tel.: +1 920 339-2222
Fax: +1 920 339-2233
info@optima-usa.com
www.optima-usa.com

OPTIMA packaging machines, S.A. de C.V.
San Jorge 198
Col. Pedregal Santa Úrsula
Del. Coyoacán
C.P. 04600 México, D.F. México
Tel.: + 52 55 5421-0271
Fax: +52 55 5610-4452
info@optima-mex.com
www.optima-mex.com

OPTIMA do Brasil Máquinas de Embalagem Ltda.
Rua Joana Foresto Storani, 500
13280-000 Vinhedo - SP, Brazil
Tel.: +55 19 3886-9800
Fax: +55 19 3886-9810
info@optima-bra.com
www.optima-bra.com

OPTIMA India packaging machines Pvt. Ltd.
No. 2, 2nd Floor, Sri Datri Nivas
Nagawara Circle, Outer Ring Road
Opp. Manyata Softech Park
Bengaluru – 560045
Karnataka, India
Tel.: +91 80-40854449
info@optima-ind.com
www.optima-ind.com

OPTIMA Japan Co. Ltd.
362 Shimizu-cho
Kawaramachi-dori
Nijio-agaru, Nakagyo-ku
Kyoto 6040911, Japan
Tel.: +81 75 223-1588
Fax: +81 75 223-1595
optima@alles.or.jp

OPTIMA KOREA CO., LTD
SUITE 1107, 6 WIRYESEONG-DAERO,
SONGPA-GU, SEOUL, KOREA, 138-827
Tel.: +82 2 414 7105
Fax: +82 2 414 1908
info@optima-kr.com
www.optima-kr.com

OPTIMA Packaging Machines (Shanghai) Co., Ltd.
No. 695 Fengmao Road
Malu Town, Jiading District
Shanghai 201801, China
Tel.: +86 21 6707 0888
Fax: +86 21 6707 0889
info@optima-cn.com
www.optima-cn.com

OPTIMA PACKAGING MACHINES (M) SDN. BHD.
5008 A 1st Floor
Jalan Lunas, Batu 2.5
09000 Kulim, Kedah
Malaysia
Tel.: +60 4 495 1619
Fax: +60 4 495 1697
info@optima-mal.com
www.optima-mal.com

More information:

www.optima-pharma.com

Since we are constantly working on finding new ways to optimise our state-of-the-art machines, the texts, illustrations and figures in this prospectus are not binding and exemplar.

10405381/4/EN

OPTIMA pharma GmbH
Otto-Hahn-Str. 1 | 74523 Schwaebisch Hall | Tel.: +49 791 9495-0 | Fax: +49 791 9495-2610 | info@optima-pharma.com | www.optima-pharma.com