



Thermoforming packaging machines in the MULTIVAC Clean Design™

Flexible packing of pharmaceutical and biotech products



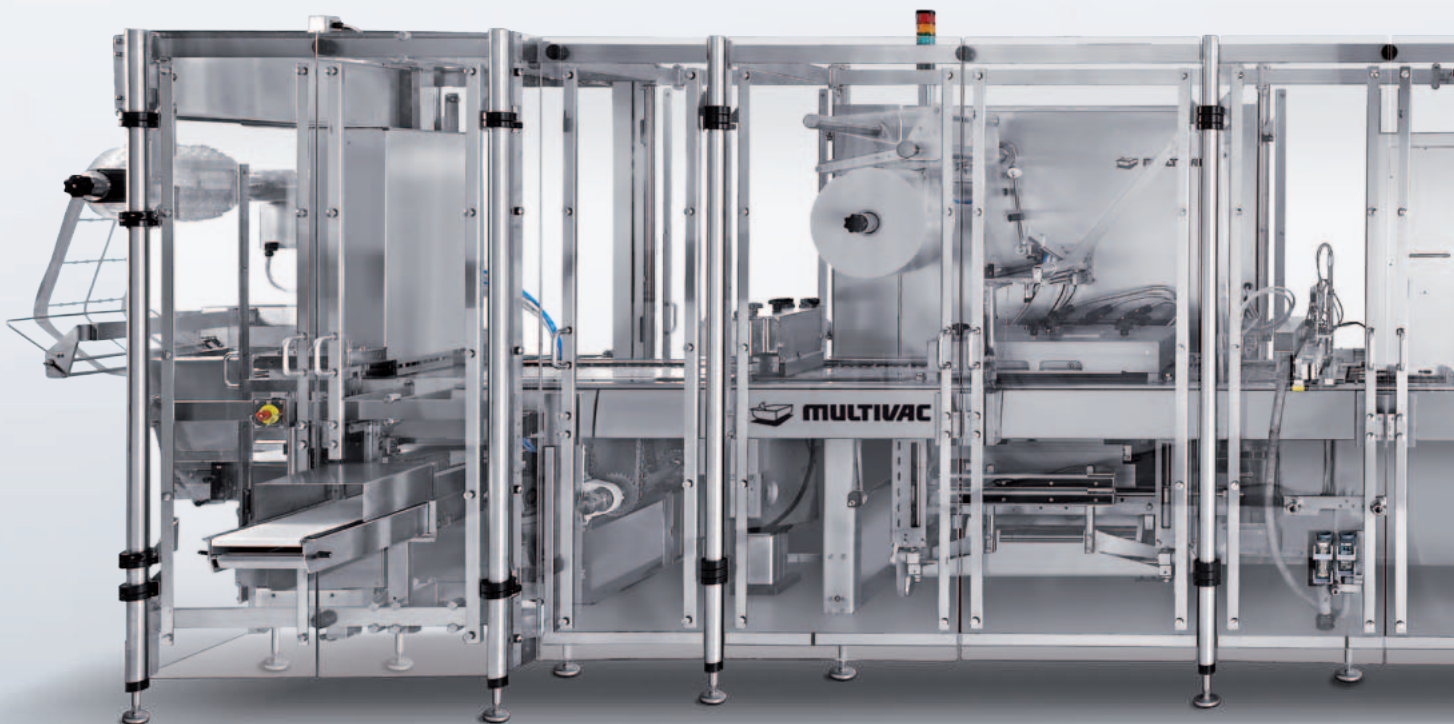
MULTIVAC

BETTER PACKAGING

Flexible packing of pharmaceutical and biotech products

The share of innovative biotechnology products is increasing in the pharmaceuticals market. Due to this trend, pharmaceuticals are becoming increasingly more complex and individually tailored to patients. This means that there are even greater demands placed on pharmaceutical packaging solutions regarding flexibility, packaging materials, pack sizes and the atmosphere in packs.

Thermoforming packaging machines in the MULTIVAC Clean Design™ are designed for the special demands of the pharmaceutical and biotech industries, and they incorporate new, ground-breaking developments for the packing of sensitive and active products.

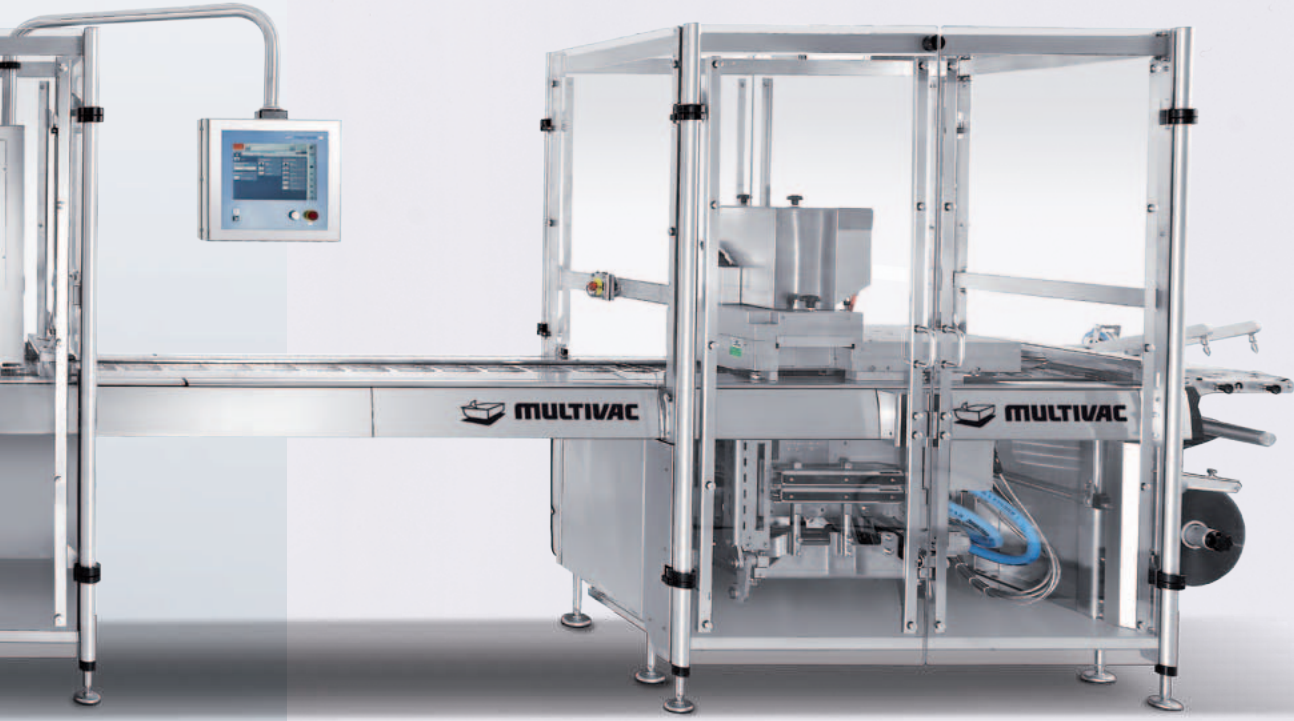




The machine concept ensures the strict separation between the product processing area and the machine technology area. It achieves a unique level of efficiency, even with small batch sizes, and it offers the greatest possible degree of process reliability, since it ensures that, among other features included, a complete Line Clearance can be achieved.

A thermoforming packaging machine in the MULTIVAC Clean Design™ provides the greatest possible support for the packing of products to GMP guidelines, particularly regarding cleanability, process reliability and reproducibility when packaging

- Sensitive products
- Active products
- Combination packs
- Modified atmosphere packages (MAP)



Flexibility

Thermoforming packaging machines in the MULTIVAC Clean Design™ offer a high level of flexibility in relation to formats, packaging materials and pack atmosphere. The quick conversion of the machine, even for small batch sizes, can be achieved by a simple format change.

- Production of complex formed packs
- Quick and simple format change
- Packaging in flexible and rigid films without any conversion
- Packaging in paper, Tyvek® and aluminium multilayer films
- Modified atmosphere packaging (MAP)
- A format range, which can be defined with flexibility
- Extended format sets
- Large forming depth range

Modular construction

The modular construction gives a high level of flexibility to the machine design.

- Flexible machine design
- Capability for simple extension and upgrading
- Flexible automation of part processes
- Flexible positioning of the product discharge
- Seamless integration of automation, identification and inspection solutions

Sensitivity

The innovative machine concept enables a strict separation to be achieved between the product processing area and the machine technology area. Transparent enclosures with large-area doors guard against direct access and environmental influences. The enclosures also offer perfect visibility and cleanability.

- Production of modified atmosphere packs (MAP) with controlled residual oxygen content
- Packs equipped with the widest range of functions
- Production of complex formings for maximum product protection
- Seamless integration of inspection systems
- GMP and GAMP compliance
- Line Clearance

Tyvek® is a registered trademark of DuPont





Process reliability

Thermoforming packaging machines in the MULTIVAC Clean Design™ are equipped with the proven MULTIVAC IPC machine control to ensure reliable and reproducible packaging results.

Precise IPC control

- Reproducible, verifiable and visualized processes
- Sensitive monitoring and independent control of all the critical individual parameters
- Ethernet interfaces for data exchange and data backup

Secure user identification

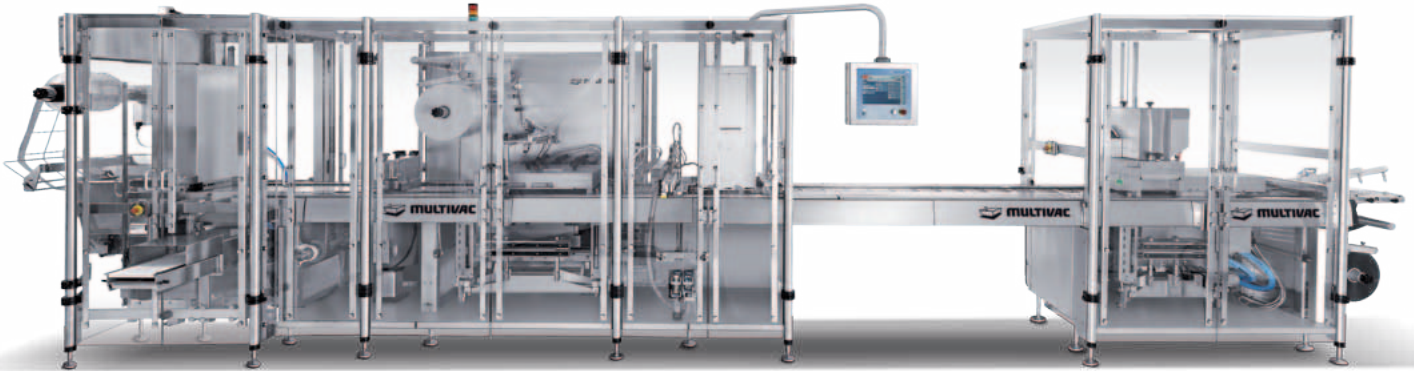
- Process and access control through user identification, for example by means of RFID chip card and entry to pre-defined user levels
- Traceability through recording of parameter changes by individual users

Reproducibility

To ensure maximum reproducibility, thermoforming packaging machines in the MULTIVAC Clean Design™ are not only trend-setting with regard to the machine control but also in their mechanical components:

- Optimised lifting units ensure a high level of sealing pressure and an even distribution of pressure
- The drive system of the transport chain guarantees maximum positioning accuracy of the packaging materials by means of a servo motor
- The innovative machine concept enables a strict separation to be achieved between the product processing area and the machine technology area. This ensures a complete Line Clearance

Technical specifications and equipment options



Technical data:

Nominal machine width MNB	285, 320, 355, 420 mm Optional: MNB 220 - 420 mm in increments of 5 mm
Cut off lengths	< 600 mm without pre-heating and without drawer < 400 mm with pre-heating and/or drawer < 275 mm with double pre-heating < 350 mm with complete cutting unit
Max. forming depth	< 120 mm, subject to the equipment of the machine < 60 mm with complete cutting unit
Reel diameter	Bottom web: Max. 500 mm (optional Jumbo max. 1,000 mm) Top web: Max. 500 mm
Compressed air	min. 7 bar, consumption depending on the equipment
Electrical connection	3 x 400 V, 50 Hz / 3 x 220 V, 60 Hz (other voltages on request)
Capacity	15 - 20 cycles per minute

Equipment options:

- GMP conform Design
 - Separation of process and technical area
 - Bottom plates in non-knee-free area
- Knee-free area 1,500 - 5,000 mm in increments of 500 mm
- Different cutting systems, e.g. complete cut
- Uplift stroke forming and sealing 25 mm
- Central air exhaust chamber
- Expandable with different direct printing systems
- Different inspection and identification systems
- Different automation solutions for loading and unloading
- Traceability Software, data collection
- FDA CFR 21 Part 11, Audit Trail
- Production of Modified Atmosphere Packages (MAP)
- Servo plug die

MULTIVAC services

Integrated packaging solutions

As a global company with many years of far-reaching experience, MULTIVAC offers packaging solutions which are far more than just a perfectly functioning machine. Your requirements and our expertise come together to provide a packaging solution which is specially tailored to your needs and which we support with a comprehensive range of services.

Validation

It is our goal that our packaging solutions will fulfil your demands and the legal requirements as quickly, efficiently and economically as possible. To this end our team of experts offers you a wide range of support services and technical assistance. We have developed a qualification and validation package, which conforms to the GMP, GAMP 5 and ISO guidelines. This includes among other features:

- Validation schedule
- Risk analysis
- Functional specification
- Installation and Operation Qualification
- Computer validation

We also support you in the implementation of qualification and validation processes on site and will assist you in the creation of procedures for special validation and retrospective validation in the case of packaging machines which have already been installed.

Calibration

The relevant process parameters in our packaging lines can be calibrated in order to ensure reproducible packaging quality and procedures. We record the results in a calibration protocol and make the corresponding documentation available to you for the correction of measurement deviations.

FDA CFR 21 Part 11

In order to comply with the requirements of the FDA CFR 21 part 11 guideline, our IPC machine control can be equipped with the following function capabilities for the monitoring and recording of the packaging procedure:

- Personalized user administration
- Password administration
- Audit trail
- Recipe change log
- Data backup

Project management

From the initial idea to the first test run - a competent and experienced project team will be at your side during the implementation of your packaging solution, a team that will accompany you from the first consultation to the final completion of the packaging project. Our range of services is rounded off by the training of your staff and the final machine acceptance. That is not, of course, the end of our cooperation since we are always there for you.

Training

We offer comprehensive training courses for you to become familiar with the operation, maintenance and care of your machine. Training can take place either at our worldwide training centres or with you on site. The coaching is practically based and is carried out right at the machine, and you also receive the written training material at the end. This allows you to fully realize the potential of your new MULTIVAC packaging solution.

MULTIVAC is there for you on site worldwide.

More than 900 sales advisors and service technicians work worldwide in over 65 daughter companies. We are present on all continents and in all important markets. At all times and in all places we offer you expert advice and a comprehensive range of services covering all areas of packaging, as well as supporting you in achieving the best possible and most effective overall solution. Our technical service, combined with a rapid availability of spare parts, ensures that all MULTIVAC machines installed worldwide are at maximum readiness. You can trust us!

www.multivac.com