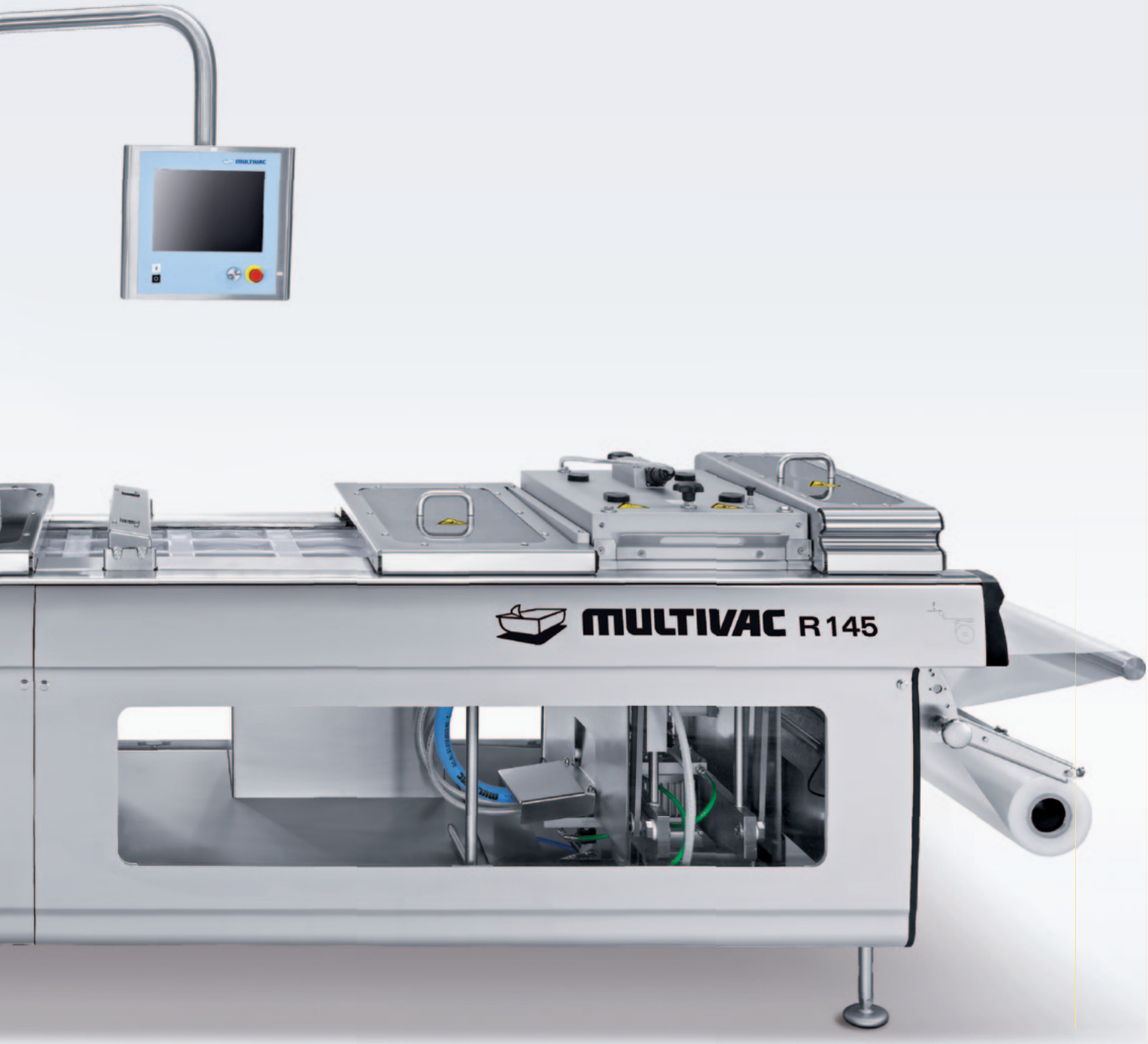
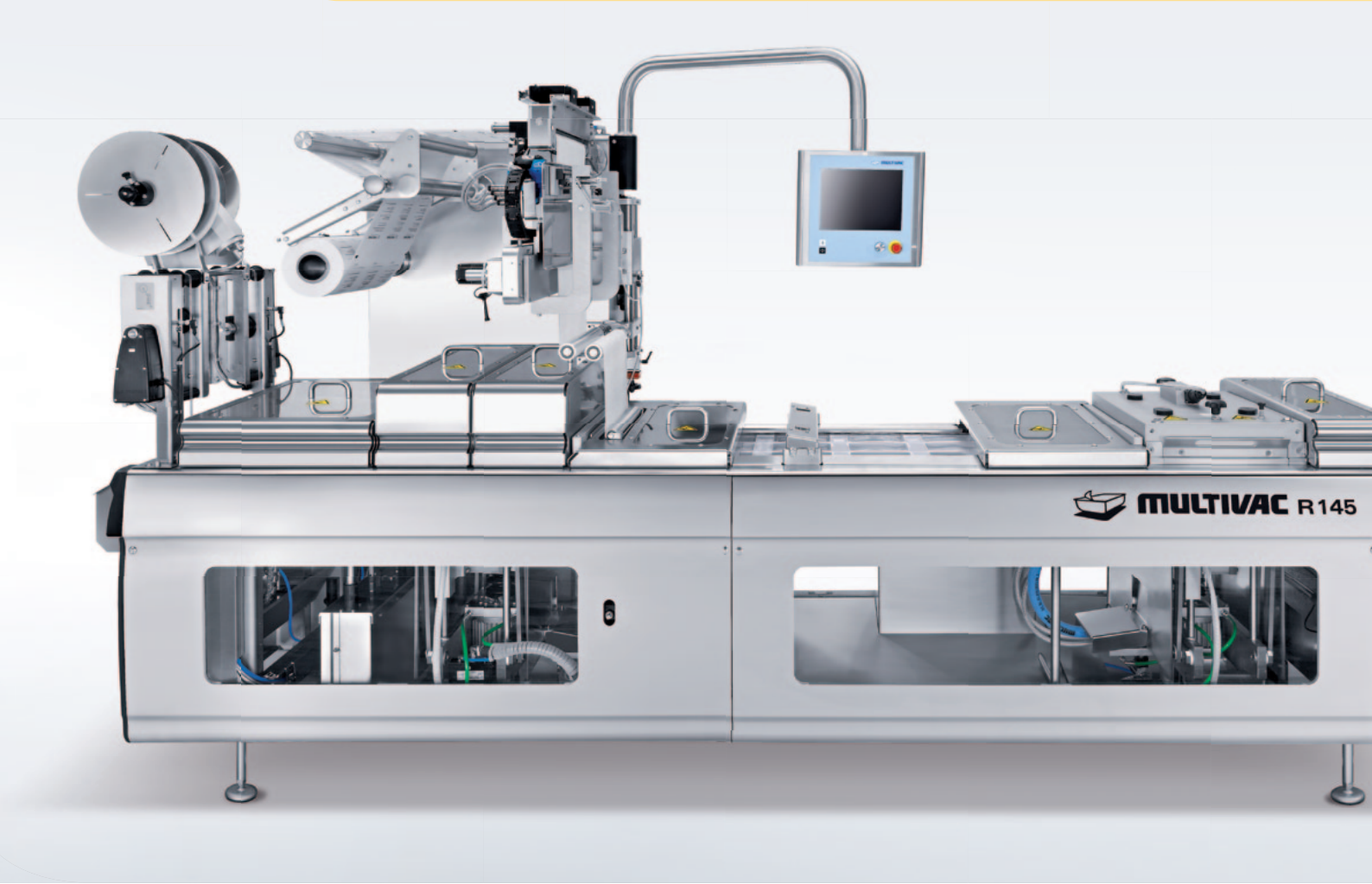



# Thermoforming packaging machine R 145 with MULTIVAC Clean Design™

Maximum process reliability and cleanroom suitability

MULTIVAC
BETTER PACKAGING




# Thermoforming packaging machine R 145 with MULTIVAC Clean Design™

## Maximum process reliability and cleanroom suitability

The R 145 with MULTIVAC Clean Design is a packaging system that has been configured to meet the special requirements of the medical sector and pharmaceutical industry.

A precise feeding system, optimized lifting units, as well as the innovative MULTIVAC Clean Design™ ensure that the R 145 packages medical sterile goods in compliance with GMP requirements. The R 145 leads the field, specifically in respect to packaging quality, process reliability and cleanroom suitability.

The R 145 thermoforming packaging machine with MULTIVAC Clean Design™ specifically offers

- GMP compliance and process reliability
- Consistently high, measurable and reproducible packaging quality
- Cleanroom suitability
- Packaging of products within a modified atmosphere with a controlled oxygen content
- Flexibility in the use of very diverse packaging materials
- Fast format change variability
- Ease of use with the innovative MULTIVAC HMI 2.0 user interface



## Thermoform packaging

The thermoforming packaging process is a particularly efficient and reliable packaging solution. The production, filling and sealing of packs is automatically performed by a single packaging machine. The processes are reproducible, controllable and traceable.

Logically, the most suitable packaging materials for optimum use in thermoform packaging are packaging materials on reels, such as single-layer and composite films, paper and non-woven materials.

Thermoform packaging, by virtue of its forming and sealing capabilities using die sets, enables precision shaping of the package. The combination of high sealing pressures and precisely controlled sealing temperatures ensures the final package has a secure and durable seal. A precisely defined packaging atmosphere with a controlled oxygen content, as well as the economical use of inert gases are further advantages of the thermoforming packaging process.

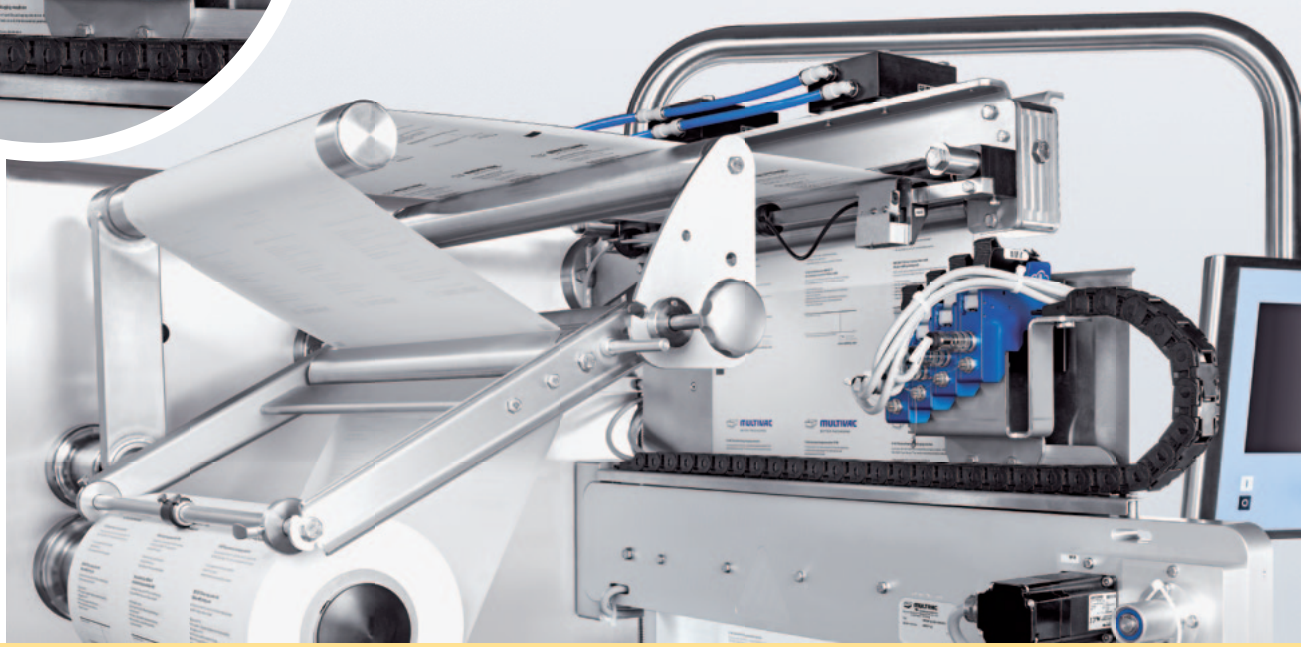
## Integration of monitoring devices

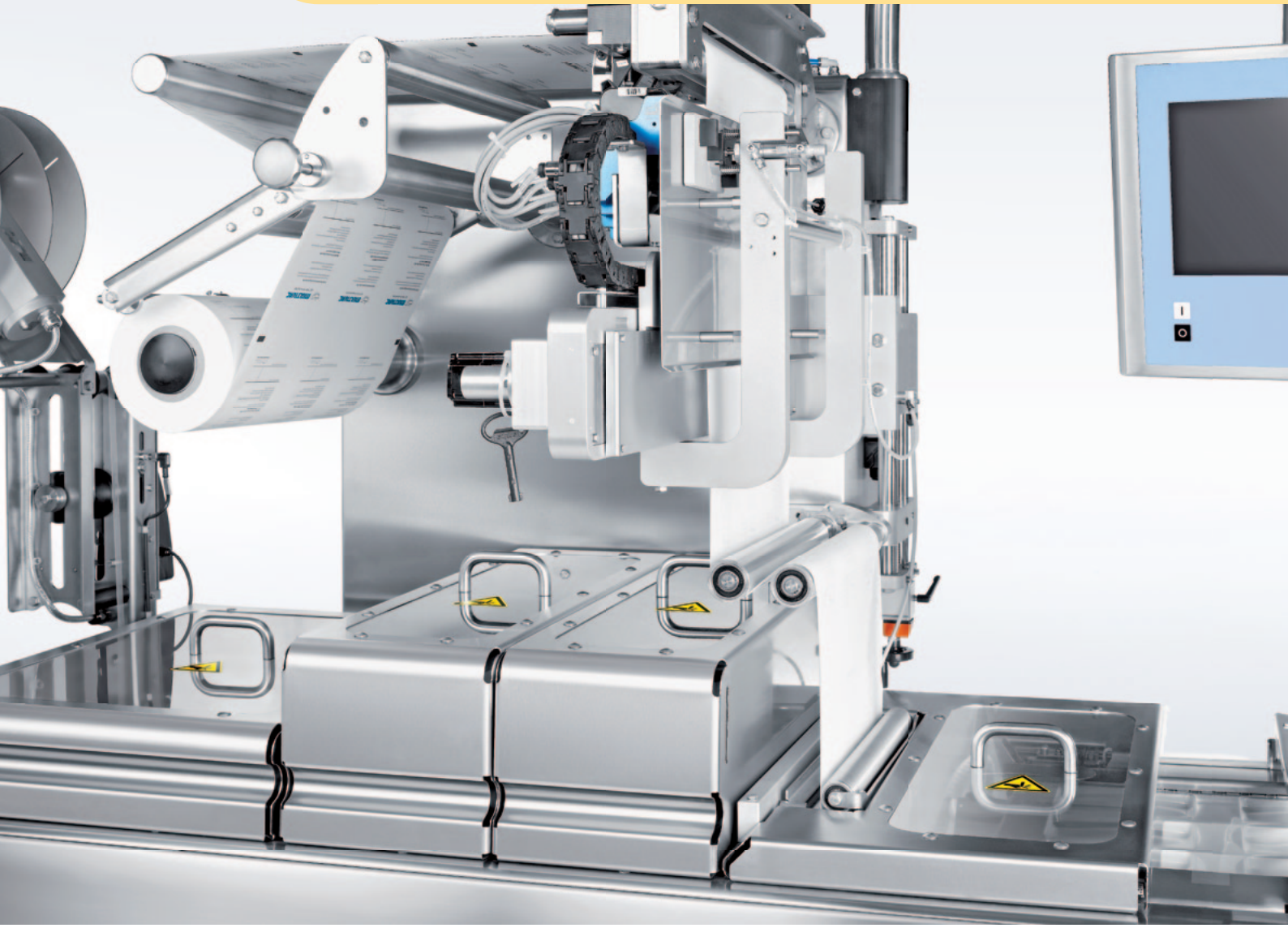
Various monitoring devices in respect to the product, the packaging materials and the packaging procedure can be integrated into the R 145, to ensure an optimal packing result.




## Integration of marking system

For purposes of package marking, the R 145 can be equipped with various marking systems.



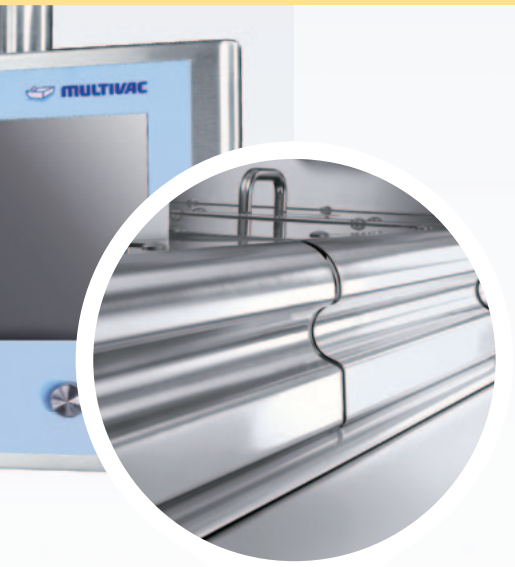


## Process reliability

In the R 145 thermoforming packaging machine, we have combined the innovative MULTIVAC Clean Design™ with groundbreaking machine control technology to ensure reliable and reproducible packing results.

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

**Secure user identification**
- Process and access control through user identification, e.g. with optional RFID chip card, and entry to pre-defined user levels
- Traceability through recording of parameter changes by individual users

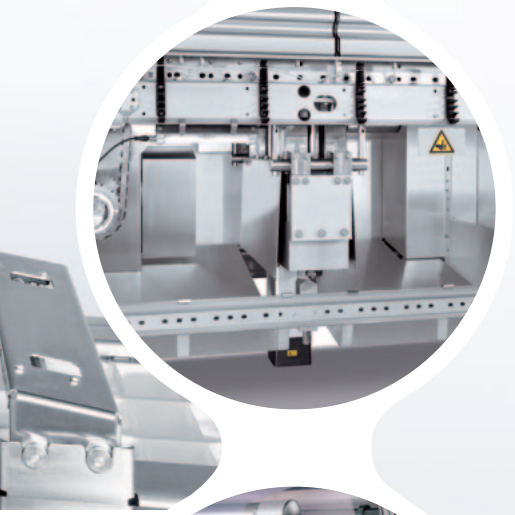



## Cleanroom suitability

With the R 145 thermoforming packaging machine, we are able to offer a versatile packaging machine that is suitable for use in a cleanroom environment, due to its GMP compliant construction and materials. The formation and accumulation of particles in the production environment is kept as low as possible.

The R 145 for packaging medical and pharmaceutical products is characterized by:

- Compact and enclosed stainless steel construction
- Ease of cleaning of the smooth and level surfaces
- Low particle emission
- Air discharge collection for pneumatic components (optional)
- Internal or external vacuum pumps or connection to central vacuum supply
- Closed cooling water circuit



## Ease of use

The user interface of the machine control, as well as all the machine elements that are to be operated by the user, are optimized for ease of use and safety.

Convenient IPC control with HMI 2.0
- Intuitive operation on a touchscreen with graphics for user guidance
- Simple setting and storing of parameters
- Process visualization on the touchscreen
- > 200 memory spaces for user recipes
- > 36 operating languages
- Troubleshooting support with graphics



## Reproducibility

To ensure maximum reproducibility, the R 145 is not only cutting edge with regard to the machine control, but also in its mechanical components:

- Optimized lifting units ensure an even distribution of pressure
- The drive system of the transport chain guarantees maximum positioning accuracy of the packaging material by means of a servo motor

## Flexibility

The forming and sealing dies of the R 145 with MULTIVAC Clean Design are configured for fast and reliable format changes. Accordingly, the R 145 can be utilized for the efficient packaging of virtually any batch size.

## MULTIVAC Clean Design™

The aim of the design in all machines with MULTIVAC Clean Design is maximum visibility and the avoidance of cross contamination. Accordingly, particular emphasis was placed on a machine design with the following features:

- Visibility of all process related machine areas
- Deflector plates in the inside of the machine
- Widest possible avoidance of hidden voids
- Minimum gap dimensions
- Cable and pipe work routing in enclosed ducts
- Protective cladding of assembly modules



## Technical data

| Technical specifications R 145 | |
|---|---|
| **Machine nominal width MNW** | 250, 285, 320, 355, 420 mm |
| **Maximum cut-off length** | die without preheating up to 400 mm<br>die with preheating: up to 270 mm |
| **Maximum forming depth** | < 110 mm, subject to the equipment of the machine |
| **Packaging material** | thermoformable, heat-sealable films, flexible or rigid, Tyvek®*, paper |
| **Reel diameter** | Max. 400 mm (optional 500 mm) |
| **Machine control** | IPC 06 with 12 inch LCD touchscreen display and graphic user interface HMI 2.0 |
| **Electrical connection** | 3 x 400 V, 50 Hz / 3 x 220 V, 60 Hz<br>(other voltages possible, subject to consultation) |
| **Air pressure** | min. 7 bar, depending on the equipment of the machine |
| **Cooling water** | min. 1,5 bar, consumption depends on the equipment of the machine |
| **External measurements**<br>**Frame length**<br>**Machine width**<br>**Discharge conveyor**<br>**Infeed line** | <br>2500, 3000, 3500, 4000, 4500, 5000 mm<br>approx. 650 mm + machine nominal width min. 970 mm<br>depends on the basic machine<br>depends on the cut-off length and the machine configuration |

* Tyvek® is a registered trademark of DuPont™

| Equipment options |
|---|
| Measuring hole for calibration |
| Central air exhaust chamber |
| Film discharger with pneumatic mandrel |
| Expandable with direct printing systems, e.g. MULTIVAC MR296 |

# Our service

Our aim is to fulfil your requirements reliably and efficiently with our packaging solutions. To this end our team of experts offers you a wide range of support services and technical assistance.

**Validation**
Our comprehensive validation package complies with the relevant GMP and ISO guidelines. This includes, among other things:

- Risk analysis
- Functional specification
- Software design specification
- Hardware design specification
- Installation Qualification
- Operation Qualification

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**
In order to ensure the integrity of reproducible processes and package quality, the relevant process parameters in our packaging procedures are calibrated. We record the results in a calibration protocol and make the corresponding documentation available to you for correction of measurement deviations. (Optional Package)

**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 knowledgeable and experienced project team will be at your side during the implementation of your packaging solution. The Multivac team will be there for you from the first day of brainstorming to the ultimate completion of your packaging project. (optional services)

**Training**
We offer comprehensive training courses for you to become familiar with the operation, maintenance and care of your machine. This will enable you to realize the full potential of your MULTIVAC packaging solution.

**Service**
Worldwide there are over 800 MULTIVAC experts in the field: around 300 sales advisors to develop the most efficient packaging solutions with our customers, as well as more than 500 service technicians for technical support, retrofitting and training.



**www.multivac.com**

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