



MEDIPACKER TS

Heat-sealing machine for medical blister

MEDIPACKER TS 3535

MEDIPACKER TS 5035

MEDIPACKER TS 7035

Qualifiable to the requirements of the FDA and GMP (DQ/IQ/OQ/PQ)


MEDIPACK AG
M E D I C A L P A C K A G I N G



MEDIPACKER TS

This table model, with its compact and durable design, has been specially developed for the medical industry and use in clean room areas. The three process parameters Time, Pressure and Temperature are regulated to the tightest tolerances so that the result is a high quality package.

How the machine works

The filled blister packs are placed in the support plate. The die-cut lid is placed on the blister pack; positioning is by means of pins. The carriage is pushed to its rearmost stop. The sealing cycle is initiated automatically. The carriage is pulled back again after the sealing cycle.

The MEDIPACKER TS is a universal heat-sealing machine with the highest level of control for sealing preformed Trays (blisters) with die-cut lids made of Tyvek®, Medical paper or compound foil

Highlights of the MEDIPACKER TS:

- Easy programming of the seal parameters using the Touch Screen.
- Actual and desired values of the seal parameters are shown on the display as a number and a bar graph.
- The sealing time starts right after reaching the nominal force and not before; actual sealing time achieved is shown.
- When the MEDIPACKER TS is ready to seal the display becomes green.
- The Touch Screen can be locked with a numeric code.
- A redundant parameter monitoring function is available as an option.
- The exhaust air is collected and filtered for use in clean rooms down to class 100.
- The production data can be printed out over an interface (option).
- Fast tool change, approximately 5 minutes.
- A tool detection function is available as an option.
- Qualification of the machine in accordance with the requirements of the FDA/GMP (option).
- All 3 parameters (Time/Pressure/Temperature) can be calibrated.

Sealing tools

- The sealing tools are manufactured from aluminum and consist of a lower plate (Nest) and a seal plate.
- The quantity of blisters sealed per operation depends not only on the size of the packing, but on the entire seal surface area, the machine is capable of delivery 36KN force every cycle.
- The tools are designed and milled using a CAD/CAM package.
- The anodized receiving plate (Nest) is equipped with grooves into which the specially developed silicone profile (different standard sizes) is fitted. You can replace the seal rubbers yourself when necessary.
- The seal plates have a scratchproof, non-adhesive coating.
- The feather/spring pins are completely made of INOX and are exchangeable as spare parts.
- Optimal process parameters are tested.

Qualification

For the qualification of the heat-sealing machine MEDIPACKER TS we provide a folder containing the following documents:

- Qualification plan
- Quotation including brochure
- DQ/IQ inspection report
- Calibration of sealing pressure, temperature and time (OQ)
- Optional: Sealingseam qualification for each individual sealing tool incl. printouts of the peel force measurements
- Recommended sealing parameters
- Defect list from the qualification process
- Certificates for the force, temperature and time measuring devices
- Operating instructions
- EC declaration of conformity
- Sealing tool drawings
- Final report
- Logbook



Roll-Table

- Attractive design and high-quality materials
- Clean fitting of up to 5 sealing tools
- Flexible application thanks to rollers



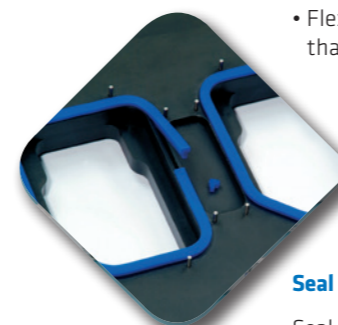
Fast tool change

It takes approximately 5 minutes



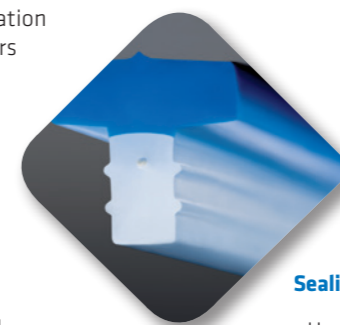
Optional

Seal statistics can be printed via printer, blue-tooth or PC



Seal tools

Seal rubbers and feather/spring pins are exchangeable as spare parts



Sealing rubber

- Homogeneous material distribution thanks to track line
- Optimum sealing results thanks to soft upper section
- Easy fitting thanks to hard base frame



Packaging Validation

A qualified machine and sealing tool is necessary for validations. The qualification report becomes a component of the whole process validation report.

MEDIPACKER TS 3535

Width	470 mm
Depth	420 mm (with guide Bars 710 mm)
Height	660 mm
Weight	112 kg without tools
Seal surface	350 x 350 mm Max. depth of Blister 105 mm



MEDIPACKER TS 5035

Width	620 mm
Depth	420 mm (with guide Bars 710 mm)
Height	660 mm
Weight	135 kg without tools
Seal surface	350 x 500 mm Max. depth of Blister 105 mm



MEDIPACKER TS 7035

Width	840 mm
Depth	940 mm (with guide Bars 970 mm)
Height	890 mm
Weight	225 kg without tools
Seal surface	350 x 700 mm Max. depth of Blister 135 mm



Design

Sealing temperature

rust-free INOX construction, Aluminium parts anodized
Digitally programmable up to max. 190 °C
feedback control accuracy at 130 °C = ± 1.0 °C measured at the hotplate
PID feedback control system

Sealing force

Programmable via touch screen from 6 kN to 36 kN (up to 54 kN as an option for the models 5035 and 7035), adjustable in 1 kN steps, repetition accuracy within 0.5 kN

Sealing time

Programmable from approx. 1.0 to 9.9 seconds, each 0.1 second adjustable
repetition accuracy better than 0.15s

Output

Approx. 12 Cycles/Minute, without placing and removal of Trays

Compressed air connection

0,6 Mpa/6 bar, tube outside 12 mm, tube length 3 m

Compressed air must be supplied filtered and dry

Compressed air consumption

The consumption per cycle at 16,5 NL to 0,5 MPa

Electrical connection

230 VPNE 50/60 Hz, max. 2300 VA/MEDIPACKER TS 7035; 3 x 400 V, 50 Hz, max. 4100 VA

Options

Roll-table with integrated tool storage system, Interface for printer, tool identification, Program memory, Qualification of the system, Blister depth of 150 mm, Automatic drawer drive for TS 5035 and 7035, Sealing lid from a film roll

Warranty

Two years on the Sealing Press – not including wearing parts (seal rubbers and pins)
Transportation and travelling charged at cost

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Certified to ISO 9001:2008
and ISO 13485:2012
Technical subject to change

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