

### **MEDIPACKER TS 3535**

Width 470 mm Depth 420 mm

112 kg without tools Weight Seal surface 350 x 350 mm

Max. depth of Blister 105 mm

(with guide Bars 710 mm)



#### **MEDIPACKER TS 5035**

620 mm 420 mm

660 mm 135 kg without tools 350 x 500 mm

(with guide Bars 710 mm)

Max. depth of Blister 105 mm Max. depth of Blister 135 mm



# 840 mm

**MEDIPACKER TS 7035** 

(with guide Bars 970 mm)

225 kg without tools

350 x 700 mm

840 mm

940 mm

890 mm



# **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)

rust-free INOX construction, Aluminium parts anodized Design

Sealing temperature Digitally programmable up to max. 190 °C

feedback control accuracy at 130 °C =  $\pm$  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 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

Sealing time

230 VPNE 50/60 Hz, max. 2300 VA/MEDIPACKER TS 7035; 3 x 400 V, 50 Hz, max. 4100 VA **Electrical connection** Roll-table with integrated tool storage system, Interface for printer, tool identification, Options

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

Two years on the Sealing Press – not including wearing parts (seal rubbers and pins) Warranty

Transportation and travelling charged at cost



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Certified to ISO 13485:2016 Technical subject to change

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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.

### **Oualification**

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

- Qualification plan
- Quotation including brochure
- DO/IO inspection report
- Calibration of sealing pressure, temperature and time (00)
- Optional: Sealingseam qualification for each individual sealing tool incl.
- of the peel force measurements
- Recommended sealing parameters
- Defect list from the qualification
- Certificates for the force, temperature and time measuring devices
- Operating instructions
- EC declaration of conformity
- Sealing tool drawings
- Final report Logbook







- 5 sealing tools Flexible application
- thanks to rollers



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



Fast tool change





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



- 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