



## MEDIPACKER TSF

TRAY SEALER for sealing film from a roll

### **MEDIPACKER TS 5035F**

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 5035F**

The 3 seal process parameters, sealing time, sealing force and sealing temperature, are controlled to the tightest tolerances. The film draw-off length can be set conveniently using the touch screen in single millimetre increments. This results in high quality packs; the process monitoring complies with the latest quality assurance requirements.

**How the machine works**

The filled blister packs are placed on the support plate. The carriage is pushed to its rearmost stop. Automatically the sealing cycle is initiated and the sealing lids are punched. The carriage is pulled back again after the sealing cycle.

The MEDIPACKER TS 5035F is a universal heat-sealing machine with the greatest possible operating convenience, for the sealing of preformed trays (blisters) with a sealing film from a roll.

**Highlights of the Medipacker TS 5035F:**

- Convenient programming of the sealing parameters in the form of touch screen dialogs.
- Up to 31 programs can be called up, with the input of tolerances.
- Actual and target parameters are displayed not only as values, but also in the form of a bar chart. When the MEDIPACKER TS 5035 F is ready, the display turns green.
- The sealing time only starts once the nominal force has been reached; the elapsed sealing time is displayed.
- Sealing is not possible outside the process tolerances (display is red).
- Parameter changes are only possible in the assured (coded) range.
- The exhaust air is filtered to Cleanroom Class 100 (ISO 5).
- The production data can be printed out via an (optional) interface.
- Faster, more convenient tool change within 5 minutes (screws outside the housing).
- Qualification of the machine in accordance with the requirements of the FDA / GMP guidelines (optional).
- All 3 sealing parameters can be (re-) calibrated on site.

**Sealing tools with cutting blade**

- The sealing tools are made of aluminium with high dimensional stability and consist of a support plate and contoured sealing plate with holding plate. How you arrange the product quantity depends not only on the size of the packs, but above all on the whole sealing surface and maximum sealing force available from the packing machine. The tools are designed to suit the packs and milled with CAD/CAM.
- The anodised support plates have a groove, in which the specially-developed silicone profile (various standard widths) is fitted without adhesive. You can replace the sealing rubber yourself when necessary.
- The contoured sealing plates have a scratch-resistant, non-stick surface.
- The cutting blade for the sealing film is fitted into the contoured sealing plate. This cuts the sealing film approx. 1-2 mm outside the blister pack.
- We determine and test the optimum process parameters.

**Qualification**

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

- Qualification plan
- Quotation including brochure
- DQ/IQ inspection report
- Calibration of sealing force, temperature and time (OQ)
- Optional: Sealingseam qualification for each individual sealing tool incl. printouts of the peel force measurements
- Recommendation of welding 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



**Seal tools**

The rubber seals and spring pins of the sealing tools can be replaced easily



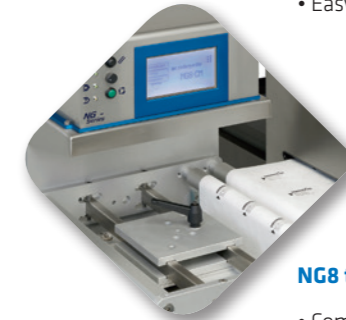
**Sealing rubber**

- 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.



**NG8 thermal transfer printer**

- Compact design
- Controlled via touch screen
- Ideal for printing variable data

**MEDIPACKER TS 5035 F**

**Width**  
**Depth**  
**Height**  
**Weight**  
**Seal surface**

920 mm  
 710 mm  
 1390 mm  
 (with trolley)  
 235 kg without tool  
 500 x 350 mm,  
 Max. depth of blister 82 mm



**Design**  
**Film roll**  
**Sealing temperature**

Frame and cover panels made of stainless steel, with aluminium parts anodised or ALTEF coated  
 Diameter max. 300 mm; core diameter 76 mm; roll width max. 300 mm  
 Programmable via touch screen from 20 °C to 190 °C, in 1 °C increments  
 Control accuracy at 130 °C +/-1.0 °C

**Sealing force**

Programmable via touch screen from 6 kN to 36 kN, in 1 kN increments  
 Repetition accuracy within 0.5 kN

**Sealing time**

Programmable via touch screen from 0.2 sec to 9.9 sec, in 0.1 sec increments  
 Repetition accuracy less than 0.15 seconds

**Film winding**

Programmable via touch screen from 0 mm to 999 mm, in 1 mm increments

**Output**

Approx. 12 cycles per minute excluding filling, insertion and removal of the packs

**Compressed air connection**

0.6-1.0 Mpa/6-10 bar, exterior hose diameter 12 mm, length 3 m  
 The compressed air supply must be filtered and dry

**Compressed air consumption**

The consumption per cycle is approx. 50 NL at 0.5 Mpa

**Electrical connection**

380 V three-phase current; max. 2700 W

**Options**

Interface for sealing cycle control (printout of the process parameters as statistics)  
 Qualification of the machine, including drawing up the qualification documentation  
 Film printer, to print the sealing film prior to processing  
 Automatic tool detection

**Warranty**

2 years for all machine parts, excluding wear parts, transport and travel costs, labour

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Certified to ISO 13485:2016  
 Technical subject to change

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