



MEDIPACKER GTS

GAS TRAY SEALER

MEDIPACKER GTS 5030

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



MEDIPACKER GTS 5030

The 3 seal process parameters, sealing time, sealing pressure and sealing temperature, are controlled to the tightest tolerances. The vacuum and gas flush values can be adjusted conveniently using the touch screen in % 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 (or filled bags) 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 automatically triggered as soon as the conditions for the controlled atmosphere are in place. The carriage is pulled back again after the sealing cycle.

The MEDIPACKER GTS is a universal heat-sealing machine with the greatest possible operating convenience, for the sealing of preformed trays (blisters) and bags in a controlled atmosphere.

Highlights of the MEDIPACKER GTS 5030:

- Convenient programming of the seal parameters and controlled atmospheres using touch screen dialogs.
- Up to 31 programs can be called up, with the input of tolerances.
- Actual and target parameters are displayed as a number and a bar graph. When the MEDIPACKER GTS 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 secure (coded) area.
- The production data can be printed out via an (optional) interface.
- Faster, more convenient tool change within 5 minutes (screws outside the housing).
- Compact design and highly efficient vacuum pump mean minimum cycle times.
- Qualification of the machine in accordance with the requirements of the FDA/GMP guidelines (optional).
- All 3 seal parameters can be (re-) calibrated on site.

Sealing tools with controlled atmosphere:

- The sealing tools are made of aluminium with high dimensional stability and consist of a support plate and contoured seal plate. How you arrange the product quantity per cycle depends not only on the size of the packs, but above all on the whole seal surface and the maximum sealing pressure 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. The customer can replace the seal rubber as required (e.g. if the surface becomes defective).
- The contoured seal plates have a scratch-resistant, non-stick surface.
- We determine and test the optimum process parameters ourselves. If requested, we will record the results of the peel and/or burst test prior to delivery or undertake a full validation.

Qualifizierung

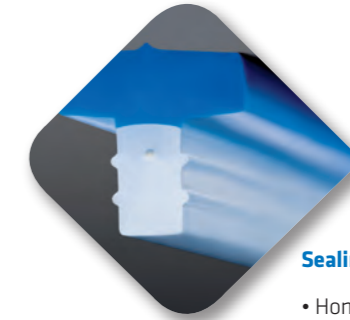
For the qualification of the MEDIPACKER GTS heat sealing machine, we provide a folder containing the following documents:

- Qualification plan
- Quotation including brochure
- DQ/IQ inspection report
- Calibration of sealing pressure temperature and time (OQ)
- Optional: Performance qualification (PQ) of each individual sealing tool (PQ), including printouts of the peel force measurements
- Recommended sealing parameters
- Defect list from the qualification process
- Certificates for the pressure, 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 heat sealing machine and appropriate sealing tool is necessary for packaging validations. The qualification report becomes a component of the whole process validation report.



Optional

Printout of the sealing statistics possible by means of a printer, bluetooth or PC



MEDIPACKER GTS 5030

Width
Depth
Height

Weight
Seal surface

620 mm
710 mm
1480 mm
(with trolley)
255 kg without tool
500 x 300 mm,
Max. depth of blister 95 mm

Design
Sealing temperature

Frame and cover panels made of stainless steel, with aluminium parts anodised or ALTEF coated
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

Vacuum

Programmable via touch screen from 0 % to 99 %, in 1 % increments
Repetition accuracy dependent on pressure

Inert gas

Programmable via touch screen from -5 % to 99 %, in 1 % increments
Repetition accuracy dependent on pressure
Not for explosive gases

Output

Approx. 3 cycles per minute excluding filling, insertion and removal of the packs
Also dependent on the vacuum level and gas flush values

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. 40 NL at 0.5 Mpa

Electrical connection

380 V three-phase current; max. 3800 W

Options

Interface for sealing cycle control (printout of the process parameters as statistics)
Qualification of the machine

Warranty

Sealing film from a film roll; the sealing film is cut out approx. 3 mm larger than the blisters
2 years for all machine parts, excluding wear parts, transport and travel costs, labour

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Certified to ISO 9001:2008
and ISO 13485:2003
Technical subject to change

www.medipack.ch