





ISO 11607.2 Validatable rotary medical sealer 4.3" colour Touch screen Traceability system Label printer, Barcode reader Remote PC connection

Rotary heat sealer for Polyethylene, Polypropylene, Polypropylene / Paper bags, Tyvek® and other heat sealable coupled materials.

Fully validable according to ISO 11607-2 standards.

Interface with barcode scanner, label printer and PC. 4.3" color touch screen and Barcode reader setting. Remote PC connection via dedicated software.

Controlled sealing speed – 6 m/min (option 4 m/min; 8 m/min).

Temperature regulation 10-220°C.

BENEFITS AND ADVANTAGES

MATERIALS

EN 868-5 bags/rolls, Tyvek[®] bags, EN 868-4 paper/paper bags, gusset bags, laminated aluminium bags, PP bags, header bags, polyethylene.

PACKAGING PROCESS VALIDATION

Accurate control of Sealing Parameters, to ensure constant and repeatable high quality over time, for maximum compliance with ISO 11607.2 Standards and international Guidelines EN-ISO TS 16775.

SAFETY

MM 9 KNURLED SEALING (FLAT OPTION) TO ENSURE A PERFECT SEAL AND EASY AND SAFE PEELABILITY.

OPERATOR INTERFACE

Equipped with a large and clear 4.3" color touch screen.

COMPLETE AND EFFICIENT TRACEABILITY

COMPLETE WITH SENSITIVE DATA TRACKING SYSTEM FOR EACH SEALED POUCH TO USB.

EFFICIENT AND EFFECTIVE INTERFACES

USB interface for connection to standard USB pendrive for loading batch, operator, catalogue, recipes, saving traceability data, updating heat sealer firmware

RS 232 serial port for connection to barcode reader, label printer, remote PC.

EFFICIENT PRINTING

All the required data can be printed with the label printer connected to the sealing machine in a simple, fast and safe way.

SANITIZATION AT THE HIGHEST LEVELS

AISI 304 STAINLESS STEEL COVER FOR MAXIMUM SANITIZATION.

ENERGY SAVING

DESIGNED AND BUILT FOR PROCESS OPTIMIZATION IN FULL COMPLIANCE WITH ENERGY SAVING EFFICIENCIES.





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Accessories

Motorized conveyor belt PS 654 workt table RL 80 sliding roller conveyor Barcode Reader PRN 2000 label printer

COMPLIANCE

UNI EN ISO 11607.2 UNI EN 868-5: 2019 EN ISO TS 16775 DIN-58953 7 Direttive 2006/42/EC-2014/30/UE-2014/35/UE UNI/TR 11408:2011 Sterilization Guidelines-MEMO 5 Produced in a Company certified with the UNI EN ISO 9001:2015 Quality System

TESTING AND VALIDATION SERVICES

Gandus Saldatrici offers a range of Testing and Validation Services to ensure safe and reliable daily monitoring of medical sealing machines for sterilization pouches in accordance with ISO 11607.1.2 and ASTM F1929 Standards.







ISO 11607.2 VALIDATABLE ROTARY MEDICAL SEALER 4.3" COLOUR TOUCH SCREEN **TRACEABILITY SYSTEM** LABEL PRINTER, BARCODE READER **REMOTE PC CONNECTION**

GENERAL FEATURES

STAINLESS STEEL FRAME PAINTED STEEL FRAME BUILT-IN ADJUSTABLE GUIDE ADJUSTABLE FREE EDGE SEALING ROTARY SEALING KIND OF SEALING: KNURLED, FLAT AS OPTION Sealing width 9 mm SEALING LENGTH UNLIMITED Seal distance from the edge MM 35 MIN) **HEAT SEALABLE MATERIALS** POUCHES/REELS EN 868-5 TYVEK[®] POUCHES/REELS PAPER POUCHES EN 868-4 **GUSSETED POUCHES/REELS** LAMINATED AL POUCHES **PP** pouches HEADER BAGS Polyethylene ULTRA[®] POUCHES/REELS ISO 11607-2 SEALING VALIDATION THROUGH AUTOMATIC CRITICAL SEALING PARAMETERS CONTROL SEALING TEMPERATURE CONTROL SEALING FORCE CONTROL THROUGH LOADCELL Speed control SEALING PARAMETERS RECORDING SEALING PARAMETERS VISUALIZATION OVERHEATING TEMPERATURE PROBE SEALER FUNCTIONING DIAGNOSTIC AND CHECK Alarm/stop temperature tolerance +/-5 °C (DIN 58953-7) ALARM AND STOP ADJUSTABLE TOLERANCE Force alarm and stop Speed/Time alarm and stop

ERRORS/OMISSIONS EXCEPTED

CERTIFICATIONS/SAFETY

UNI EN ISO 11607-2 UNI EN 868-5:2009 EN ISO TS 16775 DIN 58953-7 DIRECTIVE 2006/42/EC-2014/30/EU-2014/35/EU UNI/TR 11408:2011 **STERILIZATION GUIDELINES-MEMO 5** MANUFACTURED IN A UNI EN ISO 9001:2015 QUALITY SYSTEM CERTIFIED COMPANY PARAMETERS Controlled sealing speed 6 mt/min (opt. 4 mt/min; 8 mt/ CONTROLLED SEALING TEMPERATURE 10-220°C **Reference Sealing Force 65N-105N** Temperature tolerance ± 1% Force Range 70N AUTOMATIC SEALING PRESSURE ADJUSTMENT OVERHEATING AND INTERNAL MACHINE TEMPERATURE CONTROL CALIBRATION HEATING AUTOCALIBRATION FUNCTION AUTOMATIC SELF CHECK OF THERMOCOUPLE BATTERY AND REMOTE SERVER CONDITION AT START-UP **TEMPERATURE / FORCE / SPEED CALIBRATION** SEALER SETTING PARAMETERS SETTING VIA TOUCH SCREEN/BARCODE READER OPTION) 4 CHARACTERS PASSWORD TO BLOK ACCESS GENERAL, SETTABLE, MAINTENANCE COUNTER 10 SEALING RECIPES 24 ALPHANUMERIC BATCH CODES 20 CHARACTERS 32 ALPHANUMERIC OPERATOR NAMES 20 CHARACTERS CATALOG STRING MAX 120 CHARACTERS, COMPOSABLE WITH 120 ALPHANUMERIC STRINGS OD 20 CHARACTERS **PRODUCTION DATE** ADJUSTABLE EXPIRY DATE IN DAYS, WEEKS, MONTHS DATE FORMATS D/M/Y - M/D/Y - Y/M/D - Y/M - M/Y-Y HOUR/CALENDAR FUNCTION ALARM BEEPER **PROGRAMMED MAINTENANCE**





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INTERFACES

4,3" COLOUR TOUCH SCREEN DISPLAY

ICONS MULTILANGUAGE MENU

LABELS PRINTER

RS 232 port to connection to barcode reader, labels printer, remote PC

USB port for lot loading, operator, catalog, recipes, traceability data saving, sealer firmware updating

LABELS PRINTER

Printing in alphanumeric and barcode format (code 39) of setted data

BARCODE READER

Sealer setting through barcode reader (code 39). Codes can be generated via dedicated software

REMOTE PC CONNECTION

Connection to remote PC through dedicated software to save pouches sealing parameters

ALARMS AND SAFETY

Alarm high/low temperature

Alarm high/low force

Alarm high/low speed

ALARM TRACEABILITY

Alarm machine overheating

Alarm sealer calibration

Alarm connected to diagnostic

ERRORS/OMISSIONS EXCEPTED
* MAY VARY DURING HEATING UP PHASE

TRACEABILITY THROUGH USB PENDRIVE

Saving of all sensitive data related to each sealed pouch
Роисн ID
Sealing date and time
Sealing temperature
Sealing strength
Sealing speed
Lot code
Operator name
Alarm codes
POWER SUPPLY
Power supply V 230; V 100/120 – single phase
Frequency 50/60 Hz
Average power consumption 150W*
ACCESSORIES
PS-654 Front Support Tray
RL 80 Roller Support Tray
Barcode reader
PRN 2000 Thermal transfer labels printer
Motorized transport belt
SERVICES
Seal strength test EN 868-5
Machine calibration
Maintenance
DIMENSIONS / WEIGHTS
Dimensions mm 590x270x237
Weight Kg 18

