QUALITY SYSTEM CERTIFICATION

DNV

ISO 9001

MINIRÒ H-SEAL *Evo* VP

ISO 11607.2 Validatable rotary medical sealer
Sealing parameters control
Communication Interfaces
Traceability

Compliance with
World Health Organization guidelines
World Federation for Hospital Sterilization Sciences

Rotary heat sealer for sealing medical pouches and rolls. Validable EN ISO 11607.2.

The ideal basic solution for all hospital and industrial facilities that want to equip themselves with heat sealers validatable according to ISO standards.

mm 15 sealing, rotary, multi-line or flat.

Heat sealable materials EN 868-5 pouches/rolls, Tyvek® pouches, EN 868 -4 paper/paper pouches, pouches with gussets, laminated aluminium pouches, PP pouches.

Sealing speed 10 m/min.

All operating data can be encoded on board the machine, immediately recalled from memory and easily exported via USB.

Benefits and Advantages

Packaging Process Validation

New generation hardware and software ensure accurate control of sealing parameters to guarantee maximum compliance with ISO 11607.2 standards and international EN-ISO TS 16775 guidelines.

Customized seal

Choose between version with flat seal, suitable especially for Tyvek® pouches and multiline seal, suitable for laminated and paper pouches.

Customized Advanced Safety

Choose among the reliable and well known Gandus seal widths: standard mm 15, on demand mm 12 and mm 8, for a perfect seal strength with an easy and safe peelability.

Maximum ergonomics

Built-in and adjustable entry guide.

Communications Interfaces

USB and RS 232 interfaces for effective and efficient communication with external systems.

Operator interface

Clear and intuitive interface thanks to the extensive keyboard and the bright 2-line, 16-character display.

Traceability

All operating data can be encoded on board the machine, immediately recalled from memory and easily exported via USB.

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ISO 11607.2 VALIDATABLE ROTARY MEDICAL SEALER
SEALING PARAMETERS CONTROL
COMMUNICATION INTERFACES
TRACEABILITY

COMPLIANCE WITH
WORLD HEALTH ORGANIZATION GUIDELINES
WORLD FEDERATION FOR HOSPITAL STERILIZATION SCIENCES (WFHSS).

BENEFITS AND ADVANTAGES

PRINT FACILITY
ON THE MODEL MINIRÒ H-SEAL *Evo* VP ALL THE REQUESTED DATA CAN BE PRINTED WITH A LABEL PRINTER LINKED TO THE SEALER.

SANITIZATION AT THE HIGHEST LEVELS
STAINLESS STEEL COVER FOR MAXIMUM CLEANING AND DISINFECTION.

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

MATERIALS
BAGS/ROLLS EN 868-5, TYVEK®, PAPER/PAPER EN 868-4, WITH GUSSETS, IN LAMINATED ALUMINIUM, IN PP

ACCESSORIES
PS 654 WORKTOP
RL 80 ROLLER CONVEYOR
PR H50 ROLL HOLDER COMPLETE WITH CUTTING DEVICE
PRN 2000 LABEL PRINTER

COMPLIANCES
UNI EN ISO 11607-2
UNI EN 868-5
EN ISO TS 16775
DIN-58953-7
DIRETTIVE 2006/42/EC-2014/30/UE-2014/35/UE
UNI/TR 11408
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.

gandus®
SALDATRICI
Medical Sealers Division
We care

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TECHNICAL DATA

GENERAL FEATURES

Stainless Steel frame

Painted Steel frame

Built-in adjustable guide

Adjustable free edge

SEALING

Rotary sealing

Customized kind of sealing: flat or multiline

Sealing widths: standard mm15; on demand mm12/mm8

Sealing length: unlimited

Seal distance from the edge mm 0-35

HEAT SEALABLE MATERIALS

Pouches/reels EN 868-5

Tyvek® pouches/reels

Paper pouches EN 868-4

Gusseted pouches/reels

Laminated AL pouches

PP pouches

Ultra® pouches/reels

ISO 11607-2

Sealing validation through automatic critical sealing parameters control

Temperature / Force / 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 alarm and stop

Time alarm and stop

TECHNICAL DATA

CERTIFICATIONS/SAFETY

UNI EN ISO 11607-2

UNI EN 868-5

EN ISO TS 16775

DIN 58953-7

Directive 2006/42/EC-2014/30/EU-2014/35/EU

UNI/TR 11408

Manufactured in a UNI EN ISO 9001:2015 quality system certified company

PARAMETERS

Sealing speed 10 mt/min

Max sealing temperature 200°C

Reference Sealing force 100N

Temperature tolerance ± 1%

Force Range 80-120N

Overheating control

FUNCTIONS

Microprocessor

Multilanguage menu

Starting photocell

Temperature setting

Operators / Batchs / Catalogues / Expiry dates setting

Stand by / Energy saving

Safety thermostat

On board data retention battery even with machine off

Peripheries condition and diagnostic check up at start-up

Display shutdown

Absolute / Settable / Maintenance counter

Clock and calendar function

Beeper on/off

Programmed maintenance

errors/omissions excepted

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TECHNICAL DATA

CALIBRATION
HEATING AUTOCALIBRATION FUNCTION
AUTOMATIC SELF CHECK OF THERMOCOUPLE BATTERY AND REMOTE SERVER CONDITION AT START-UP
TEMPERATURE / FORCE / SPEED CALIBRATION

INTERFACES
DISPLAY 2 LINES 16 CHT
MEMBRANE KEYBOARD
LABELS PRINTER
RS 232 PORT
USB PORT

EXTERNAL PERIPHERIES
LABELS PRINTER

LABELS PRINTER FUNCTIONS
ON/OFF PRINT
CE SYMBOLS
BARCODE
LABEL DIMENSIONS SETTING
STANDARD OR 180° ROTATION PRINT IMAGE
MULTI LABELS PRINT
SETTABLE PRINTING SEQUENCE
PRODUCTION AND EXPIRY DATE
BATCH AND OPERATOR ALPHANUMERIC CODE
CATALOGUE STRINGS
POUCH PROGRESSIVE NUMBER
POUCH AND SEALER ID
SEALING SPEED / TEMPERATURE / FORCE
SEALING REPORT PRINT

TECHNICAL DATA

TRACEABILITY AND SOFTWARE
TRACEABILITY THROUGH USB PEN DRIVE

DATABASE
TEXTS SAVING
SEALER ID SAVING
OPERATORS / EXPIRY DATE / BATCH CODE SAVING

POWER SUPPLY
POWER SUPPLY 100; 110/115; 230/240 VAC SINGLE PHASE
FREQUENCY 50/60 HZ
MULTI-FREQUENCY
AVERAGE POWER CONSUMPTION 150W[*]

ACCESSORIES
FRONT SUPPORT TRAY
ROLLER SUPPORT TRAY
ROLL HOLDER
THERMAL TRANSFER LABELS PRINTER

SERVICES
SEAL STRENGTH TEST EN 868-5
MACHINE CALIBRATION
MAINTENANCE

DIMENSIONS/WEIGHTS
DIMENSIONS MM 554x270x222
WEIGHT KG 15

ERRORS/OMISSIONS EXCEPTED
* MAY VARY DURING HEATING UP PHASE