

## PURA



ISO 11607.2 VALIDATABLE ROTARY MEDICAL SEALER  
SPACE SAVING AND ERGONOMIC DESIGN  
OPERATED BY TOUCH SCREEN

THE CUTTING EDGE OF HIGH-TECH DESIGN

*COMPLIANT TO WORLD HEALTH ORGANISATION GUIDELINE REQUIREMENTS AND WORLD FEDERATION FOR HOSPITAL STERILISATION SCIENCES (WFHSS) NEW GUIDELINE*

*EU GMP ANNEX 1: MANUFACTURE OF STERILE MEDICINAL PRODUCTS*

*VALIDATABLE SEALING PROCESS ACCORDING TO EN ISO 11607-2 AND INTERNATIONAL GUIDANCE ISO/TS*

THE HIGH-PERFORMANCE SOLUTION THAT HARMONIZES FUNCTIONAL EFFICIENCY WITH DESIGN EXCELLENCE, WITH NO COMPROMISE.

SLEEK AND STYLISH DESIGN TO ALLOW YOU TO PACK MEDICAL DEVICES WITH CONFIDENCE, SPEED AND UTMOST EASINESS.

ISO 11607.2 VALIDATABLE MEDICAL ROTARY HEAT SEALER.

MANAGEMENT THROUGH 4.3" WIDE COLOR TOUCH SCREEN.

ROTARY SEALING MM 15 HEIGHT.

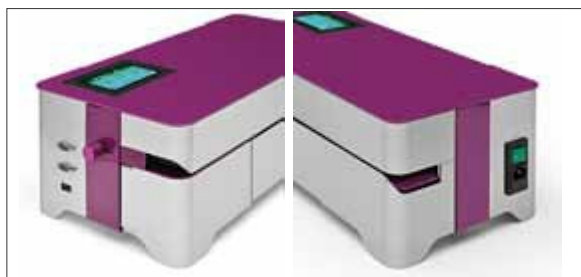
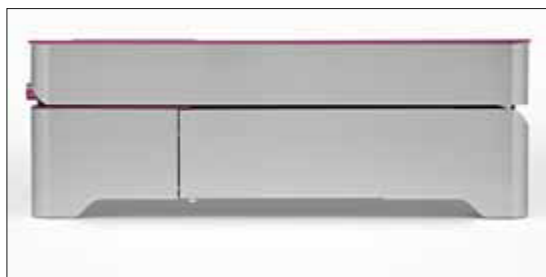
SEALING SPEED 10 M/MIN.

MAXIMUM SEALING TEMPERATURE 200°C, TOLERANCE +/- 1%.

AISI 304 STAINLESS STEEL.

10MT/MIN SPEED AND PRE-SETTING OF THE SEALING PARAMETERS FOR THE MOST USED MATERIALS FOR STERILE REPROCESSING (BOP, TYVEK, ULTRA) MAKE PURA THE BEST CHOICE IN TERMS OF VERSATILITY AND COST EFFICIENCY.

SEAL YOUR COMMITMENT TO QUALITY AND RELIABILITY WITH STYLE.



*PRODUCT DESIGN AND ENGINEERING DEVELOPED*

*WITH SCIENTIFIC SUPPORT OF POLITECNICO DI MILANO, DESIGN DEPARTMENT.*

## PURA

ISO 11607,2 VALIDATABLE MEDICAL ROTARY SEALER  
SPACE SAVING, OPERATED BY TOUCH SCREEN

THE CUTTING EDGE OF HIGH-TECH DESIGN

### ADVANTAGES AND BENEFITS

#### PACKAGING PROCESS VALIDATION

NEXT-GENERATION HARDWARE AND SOFTWARE FOR ACCURATE TEMPERATURE CONTROL. COMPLIANT WITH ISO 11607.2 STANDARDS AND INTERNATIONAL GUIDELINES EN-ISO TS 16775.

#### CUSTOMIZED SEAL

CHOOSE BETWEEN FLAT SEAL, SUITABLE ESPECIALLY FOR TYVEK<sup>®</sup> POUCHES AND MULTILINE SEAL, SUITABLE FOR LAMINATE AND PAPER POUCHES

#### SAFETY

MM 15 GANDUS MULTI-LINE SEALING TO GUARANTEE IDEAL SEALING AND EASY, SAFE PEELING.

#### MAXIMUM ERGONOMICS

BUILT-IN ENTRY GUIDE AND DOUBLE ACCESS, TOP AND FRONT, FOR QUICK AND EASY MAINTENANCE.  
FRONT DOOR FOR EASIEST PRINT CARTRIDGE REPLACEMENT

#### EFFICIENCY AND EFFECTIVENESS IN COMMUNICATION

USB AND RS 232 INTERFACES FOR EFFECTIVE AND EFFICIENT COMMUNICATION WITH EXTERNAL SYSTEMS.

#### COMPLETE AND AUTOMATIC TRACEABILITY

COMPLETE TRACEABILITY OF ALL PROCESS DATA WITH AUTOMATIC RECORDING TO STANDARD USB MEDIA.

#### OPERATOR INTERFACE

THE LARGE 4,3" COLOUR TOUCH SCREEN (OPERABLE EVEN WITH GLOVES) AND THE SPECIFICALLY DEVELOPED SOFTWARE REPRESENT THE PERFECT INTERFACE TO GUARANTEE THE OPERATOR A SIMPLE AND SAFE WORKING METHOD.

#### SECURSCAN DATA UPLOAD SOFTWARE

OPERATING VIA SCANNER, SECURSCAN DATA UPLOAD SOFTWARE ALLOWS THE DOWNLOAD OF ALL DATA ON THE SEALING MACHINE.

#### SMARTPRINT

LATEST GENERATION NEEDLE PRINTER FOR PRINTING TEXT AND BARCODES ON PACKAGING.

SIMPLE AND EFFICIENT FRONT CARTRIDGE CHANGE.

AUTOMATIC PRINT FONT SIZING IN RELATION TO THE POUCH DIMENSIONS, WITH ALARM IN CASE OF TOO SMALL POUCH.

#### SPACE OPTIMIZATION

PURA REQUIRES JUST 0,15 SQUARE METERS SPACE TO BE USED TO ITS FULL POTENTIAL.

#### SANITIZATION AT THE HIGHEST LEVELS

STAINLESS STEEL, ANODIZED ALUMINUM AND ERGONOMIC DESIGN WITH ESSENTIAL LINES FOR MAXIMUM CLEANING AND DISINFECTION.

#### ENERGY SAVING

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

## PURA

ISO 11607,2 VALIDATABLE MEDICAL ROTARY SEALER  
SPACE SAVING, OPERATED BY TOUCH SCREEN

THE CUTTING EDGE OF HIGH-TECH DESIGN

### NEW FIRMWARE FOR:

- COPY OPERATOR, BATCH AND CATALOG LIBRARIES STORED ON A USB STICK
- PERFORM A QUICK SEARCH FOR A CATALOG STRING BY TYPING THE INITIAL LETTERS OF THE STRING.

**THE NEW FIRMWARE CAN BE IMPLEMENTED ON ALL MACHINES PRODUCED SO FAR VIA USB STICK.**

### MATERIALS

PURA IS IDEAL FOR SEALING OF ALL HEAT-SEALABLE STERILE BARRIER SYSTEMS, TYVEK<sup>®</sup>, AS WELL AS ALL NEW GENERATION PACKAGING MATERIALS.

### VERSIONS

STAINLESS STEEL AND ANODIZED ALUMINUM VERSION

STAINLESS STEEL VERSION

NO PRINT VERSION (PURA NP)

### ACCESSORIES ON REQUEST

WORK PLAN

ROLLER TRAY

ROLL HOLDER

LABEL PRINTER

BARCODE SCANNER

ETHERNET MODULE

### COMPLIANCES

UNI EN ISO 11607-2

UNI EN 868-5

EN ISO TS 16775

DIN-58953 7

DIRECTIVES 2006/42/EC-2014/30/UE-2014/35/UE

UNI/TR 11408

STERILIZATION GUIDELINES-MEMO 5

*EU GMP ANNEX 1: MANUFACTURE OF STERILE MEDICINAL PRODUCTS*

PRODUCED IN A UNI EN ISO 9001:2015 QUALITY SYSTEM CERTIFIED COMPANY

### 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 MEDICAL ROTARY SEALER SPACE SAVING, OPERATED BY TOUCH SCREEN

### GENERAL FEATURES

ANODIZED ALUMINIUM AND AISI 304 STAINLESS STEEL  
BUILT-IN ADJUSTABLE GUIDE  
ADJUSTABLE FREE EDGE

### SEALING

CUSTOMIZED KIND OF SEALING: FLAT OR MULTILINE  
SEALING WIDTH 15 MM  
SEAL DISTANCE FROM THE EDGE MM 0-35

### PACKAGING

POUCHES/REELS EN 868-5, TYVEK® POUCHES/REELS, PAPER POUCHES EN 868-4, GUSSETED POUCHES/REELS, PP POUCHES, LAMINATED AL POUCHES, ULTRA® POUCHES/REELS

### ISO 11607-2

SEALING VALIDATION THROUGH AUTOMATIC CRITICAL SEALING PARAMETERS CONTROL  
TEMPERATURE, FORCE AND SPEED CONTROL  
SEALING PARAMETERS VISUALIZATION AND RECORDING  
OVERHEATING TEMPERATURE PROBE  
SEALER FUNCTIONING DIAGNOSTIC AND CHECK  
ALARM/STOP TEMPERATURE TOLERANCE  $\pm 5^{\circ}\text{C}$  (DIN 58953-7)  
FORCE/SPEED/TIME ALARM AND STOP

### COMPLIANCES

UNI EN ISO 11607-2  
UNI EN 868-5  
EN ISO TS 16775  
DIN 58953-7  
DIRECTIVES 2006/42/EC-2014/30/EU-2014/35/EU  
UNI/TR 11408:2011  
EU GMP ANNEX 1: MANUFACTURE OF STERILE MEDICINAL PRODUCTS  
MANUFACTURED IN A UNI EN ISO 9001:2015 QUALITY SYSTEM CERTIFIED COMPANY

### EXTERNAL PERIPHERIES

LABELS PRINTER / BARCODE SCANNER  
TRACEABILITY AND SOFTWARE  
TRACEABILITY THROUGH USB PEN DRIVE  
SECURSCAN DATA UPLOAD SOFTWARE

### PARAMETERS

SEALING SPEED 10 MT/MIN  
MAX SEALING TEMPERATURE  $200^{\circ}\text{C}$   
REFERENCE SEALING FORCE 100 N  
TEMPERATURE TOLERANCE  $\pm 1\%$   
FORCE RANGE 80-120 N

### CALIBRATION

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

### INTERFACES

TOUCH SCREEN WITH 4,3" COLORS DISPLAY  
PC CONNECTION  
REMOTE CONTROL VIA ETHERNET  
LABELS PRINTER  
BARCODE SCANNER  
RS 232 PORT/USB PORT

### DATABASE

TEXTS SAVING  
POUCH / SEALER ID SAVING  
OPERATORS / EXPIRY DATE / BATCH CODE SAVING  
PRESETTABLE PROGRAMS

### FUNCTIONS

MICROPROCESSOR / MULTILANGUAGE MENU  
STARTING / PRINTING PHOTOCCELL  
SPEED AND TEMPERATURE SETTING  
OPERATORS / BATCHES / CATALOGUES / EXPIRY DATES SETTING  
STAND BY / ENERGY SAVING  
ON BOARD BATTERY  
SETTINGS / MAINTENANCE PASSWORD  
ABSOLUTE / SETTABLE / MAINTENANCE COUNTER  
CLOCK AND CALENDAR FUNCTION / BEEPER ON/OFF  
PROGRAMMED MAINTENANCE

### BUILT-IN PRINTER FUNCTIONS

1 PRINT LINE  
ON/OFF PRINT, EN / CE SYMBOLS  
AUTOMATIC PRINT ADJUSTMENT TO POUCH WIDTH / PRINT POSITION ADJ  
STANDARD OR  $180^{\circ}$  ROTATION PRINT IMAGE  
SETTABLE PRINTING FORMATS, CHARACTER DIMENSIONS, 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

### LABELS PRINTER FUNCTIONS

ON/OFF PRINT, CE SYMBOLS  
BARCODE  
LABEL DIMENSIONS SETTING AND 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  
STANDARD OR  $180^{\circ}$  ROTATION PRINT IMAGE  
MULTI LABELS PRINT

### POWER SUPPLY

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

### ACCESSORIES UPON REQUEST

FRONT SUPPORT TRAY; ROLLER SUPPORT TRAY; ROLL HOLDER  
THERMAL TRANSFER LABELS PRINTER; BARCODE SCANNER; ETHERNET MODULE

### SERVICES

SEAL STRENGTH TEST EN 868-5  
TEMPERATURE / FORCE / SPEED CALIBRATION  
MAINTENANCE

### DIMENSIONS AND WEIGHT

DIMENSIONS MM 553x264x192 / WEIGHT Kg 18

PURA

THE CUTTING EDGE OF HIGH-TECH DESIGN