



*BAND SEALERS
FOR HEALTHCARE*

**We Seal Safety
since 1954**

gandus[®]
SALDATRICI

Medical Sealers Division

We care



Technology for Safer Packaging.

PURA *Validatable Perfection through Purity*

A NEW STANDARD IN MEDICAL PACKAGING.

The perfect combination of validated performance, digital intelligence, ergonomic design and sustainable efficiency.

New generation **medical rotary heat sealer** to redefine packaging standards with **intelligent control, full digitalization,** and **energy-efficient design**, perfectly aligned with **Industry 4.0** principles.

- **AISI 304 stainless steel** construction with **essential, ergonomic lines** to ensure **maximum hygiene** and durability.
- Compact use of space (only **0.15 m²**).
- **WHO** and **WFHSS** guidelines compliance to guarantee a **Validatable sealing process** in accordance with **EN ISO 11607-2** and **ISO/TS 16775**.
- **4.3" color touch screen** for intuitive management of all process parameters.
- **New firmware** for quick data handling, USB-based updates, and easy catalog searches.
- **Complete traceability** as all sealing data are automatically stored on USB or transferred via **RS232/USB interfaces**.
- **UDI-ready** system for integration with external label printers.
- **SmartPrint system** allows direct text and barcodes print, automatically adapting font size to pouch dimensions.
- **15 mm seal** to ensure secure closure and easy peeling.
- Designed for **maximum efficiency**, the sealer combines **energy-saving technology, quick maintenance access,** and **sanitizable materials**, ensuring reliability, cleanliness, and long-term performance in sterile environments.



REBI TECH *Your Seal. Your Way. Fully Customizable.*

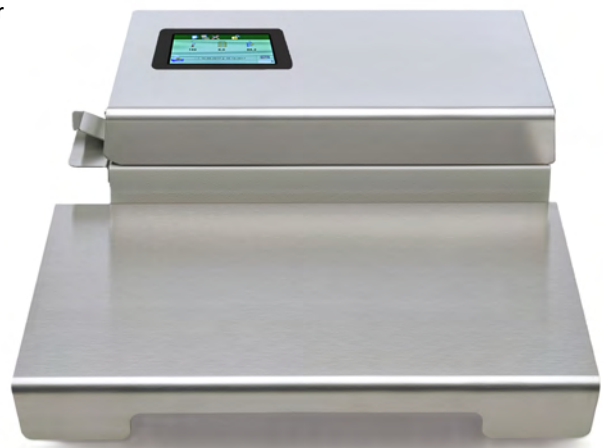
VALIDATABLE ROTARY HEAT SEALER. COMPACT. FLEXIBLE. GREEN.

Compact, fully customizable, and energy-efficient sealing solution combining validated performance with modern digital control.

A new generation high customizable of **rotary heat sealers** designed for **reliable, safe and efficient medical packaging for high production levels**.

- **Modular structure** for full customization, from basic models to most advanced configurations through accessories and optionals that allow **Validation, Traceability, Integrated Printing** possibility and **Touch screen interface**.
- **AISI 304 stainless steel construction** to ensure **maximum hygiene, durability,** and **energy efficiency**.
- **Process Validation** according to **ISO 11607-2, EN ISO TS 16775,** and **UNI EN 868-5** through top performing sealing parameters control.
- **12 mm multi-line rotary sealing** (DIN 58953.7 compliant)
- **Adjustable speeds** 8-10 m/min
- Compatibility with **Tyvek®** and all **heat-sealable sterile barrier systems**
- **USB interface** for data transfer and process recording
- **Integrated printing, traceability of sealing parameters, calibration services** as available options.

The unit complies with all relevant **EU directives** and is produced under a **UNI EN ISO 9001:2015 certified quality system**.



minirò QUBE UDI-Ready Validatable Rotary Heat Sealing System

RELIABLE. CONNECTED. VALIDATABLE.

UDI-Ready Sealing for the Future of Medical and Pharmaceutical Packaging.

This UDI-ready rotary heat-sealing system has been designed for the specific requirements of the medical and pharmaceutical industries, ensuring the highest levels of Process Validation, Traceability, and Product Identification.

- **Integrated inkjet printing unit**, to aggregate all UDI-relevant data into a **Data Matrix code**, printed directly on the sterile barrier system. Data entry via **touch screen, USB, Ethernet, 2D scanner, or RFID reader**, ensuring full integration within digital workflows.
- **Variable speed control.**
- **9 mm flat or knurled seal** compliant with **DIN 58953-7.**
- **Automatic stop function** if temperature deviates from preset range.
- **Validatable sealing process** full compliance with **EN ISO 11607-2, ISO/TS 16775** as well as **WHO** and **WFHSS** guidelines.
- **AISI 304 stainless steel construction.**
- **Benchtop** or mounted on a **motorized height- and tilt-adjustable stand versions.**
- **Synchronized conveyor belts** available for optimized workflow.
- **Dual 4.3" touch screen programming system** for intuitive setup and monitoring—with separate interfaces for **sealing data management** and **printing control.**
- **Complete Traceability** ensured through automatic recording of process parameters, with data export available via USB or MODBUS TCP/IP.
- Certified under **UNI EN ISO 9001:2015**, for **maximum safety, process reliability, and regulatory compliance**, setting a new benchmark for Validated medical and LifeScience packaging.



VALIDATION AND SUPPORT SERVICES

Comprehensive Validation Consultancy combined with advanced Testing Solutions designed to ensure process reliability and compliance with international standards.

SEAL INTEGRITY TESTS to enable you easy, quick and safe daily control of your seals to fully comply with EN ISO 11607.2, ASTM F1929, EN868-5 Annex D.

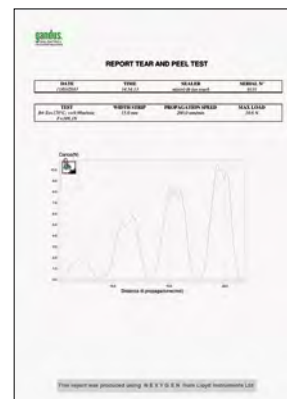
- SealCheck according to EN ISO 11607.2.
- Routine Tests according to ASTM F1929.
- Peel Strength Test according to EN 868-5 Annex D.
- **CALIBRATION SERVICES** to regularly inspect medical sealers and guarantee a Validatable Sealing Process.



STANDARDS AND CERTIFICATES

- MDR 2017/745
- EN ISO 11607.2, TS 16775
- WFHSS Guidelines
- WHO 2016
- GMP
- Cleanrooms
- EN ISO 11607.1
- EN 868-5, EN 868-4, EN 868-3, EN 868-9
- DIN 58953

- **VALIDATION CONSULTANCY SERVICE** to certify your Sealing Process is Validatable according to EN ISO 11607.2 and your sealer conforms ISO requirements. If outputs are positive IQ and OQ Certificates are issued together with relevant documents.
 - IQ Installation Qualification
 - OQ Operation Qualification



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We Seal Safety since 1954

A Tradition of Quality, Design, and Tailored Manufacturing. Precision and Craftsmanship Made in Italy

Founded in Milan in 1885 by Prospero Gandus, Gandus Saldatrici has evolved from crafting handmade paper bags to becoming a global benchmark in packaging technology.

Driven by generations of innovation and resilience, the Company entered the field of sealing machines in 1954 and, by the 1980s, had established itself as a leading reference in Medical, Pharmaceutical, and Life Science packaging.

The utmost evolution in sterilization

The key point is to clearly define the process critical parameters. In order to guarantee a seal which is conform to EN 868-5 standards, the sealer must be able to monitor and record the temperature, the force applied and the time cycle of the sealing process.

Such an equipment can be part of a sterile packaging process which is validatable according to EN ISO 11607.2 standards.

With a comprehensive range of sealing and packaging systems, Gandus Saldatrici offers top-quality, hygienic, and safe solutions built with unmatched precision, reliability, and certified performance. This dedication to innovation places the company at the forefront of sterilization technology and has established it as a leading national and international reference in medical, pharmaceutical, and life science packaging.

Its sealers are engineered to ensure seals compliant with EN 868-5 and EN ISO 11607-2 standards, continuously monitoring and recording all critical process parameters – temperature, sealing force/pressure, and time – to guarantee full process validation

Our vast experience and ongoing commitment to ensure that our wide range of equipment meets the latest requirements allows us to deliver equipment that meets the highest standards of safety and service, together with comprehensive validation services, supporting customers throughout every stage of the process.

Combining more than a century of craftsmanship with cutting-edge engineering, Gandus Saldatrici continues to shape the future of sterile packaging. A tradition of excellence that began in 1885 and continues to evolve.

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COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
= ISO 9001 =