

PACKAGING
MACHINES

FOR HEALTHCARE
PHARMA
AND LIFE SCIENCE

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

The wide Gandus Saldatrici range guarantees a top quality seal, fully complying with the EN ISO 11607.2 standards. Thanks to reliability and extra care on hygiene and safety Gandus has become national and international point of reference in the Medical, Pharma and LifeScience packaging industry.

Our vast experience, and ongoing commitment to ensure that our wide range of equipment meets the latest requirements, allows us to offer not only a range of products which can assure the highest level of safety and service, but also a range of services totally dedicated to the Validation Process.

gandus[®]
SALDATRICI
Medical Sealers Division
We care

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COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
= ISO 9001 =

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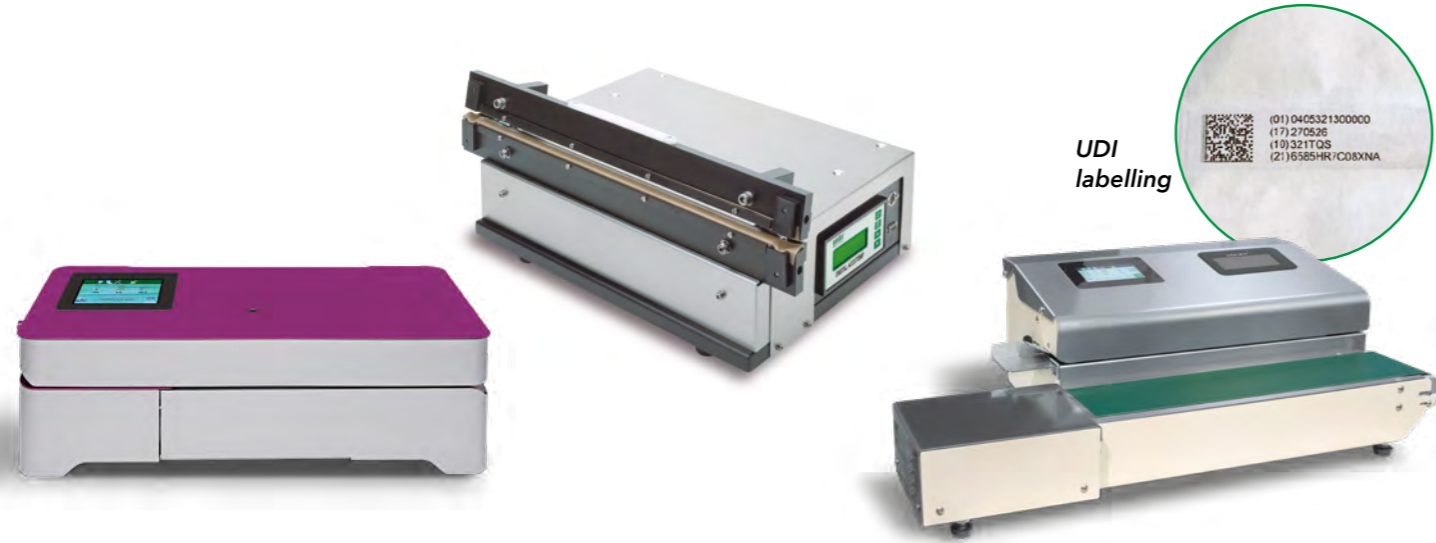
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We Seal Safety since 1954

SEALERS

- **Distinctive Style:** Gandus sealers are renowned for their distinctive style, making them stand out from the competition.
- **Customization:** tailor our sealers to perfectly match your needs with a wide range of options.
- **Comprehensive Range:** a comprehensive and extensive range of sealers to fit a wide variety of applications.
- **Ideal for Healthcare:** whether in a large hospital or a small dental clinic, our sealers are the right choice for maintaining sterile environments and ensuring product safety and integrity.
- **Ideal for Pharma and Life Science Industry:** Gandus sealers deliver top-tier quality, exceptional connectivity, and personalized service.
- **UDI ready:** prioritize meeting the most demanding UDI labeling requirements with a wipe resistant, top performing printing. Whether on the paper or clear side of your pouch.



VACUUM SEALERS

- **Vacuum Functionality:** our sealers with vacuum functionality enhance product longevity by creating MAP (Modified Atmosphere Packaging) through inert gases flushing, preserving both product integrity and quality.
- **Utmost Versatility:** Gandus vacuum machines are extremely versatile, designed to efficiently seal a wide range of materials, ensuring product integrity and safety across a wide range of applications.
- **Validation for Critical Processes:** relied upon by key industries such as pharmaceuticals, nutraceuticals and medical equipment manufacturers, Gandus vacuum function sealers offer vital solutions for sealing and preserving, with a strong emphasis on process validation for critical applications.



SPECIAL ENGINEERING

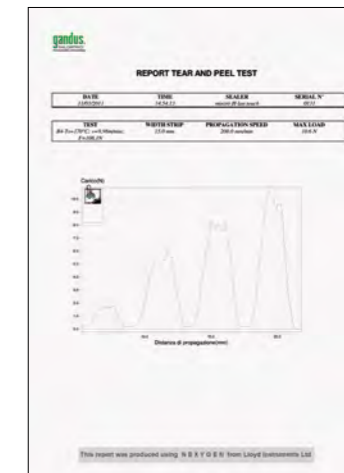
- **Highly Customized Solutions:** our special projects team is specialized in crafting packaging systems solutions tailored to the unique specifications of each customer project.
- **Support from A to Z:** our Special Engineering Department supports companies with product prototyping, design and manufacturing, from development of technical drawings to turnkey project.

We collaborate closely with you to fully understand your objectives, blending technology, expertise, and unwavering dedication. Our all-encompassing engineering, construction, management, and maintenance services are designed to deliver the optimal solution for your Company.



VALIDATION AND SUPPORT SERVICES

- **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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