



CertoSeal 200/300

User Manual

Version: 2.0

Instructional videos can be
found on our YouTube
channel:

<https://www.youtube.com/@steri24>



Dear Doctor,

Thank you for purchasing a Steri24 product – a trademark of CertoClav Sterilizer GmbH. As a family business, we have been concentrating on the development, production and trade of products for sterilization and practice hygiene since our foundation in 1961. Through our constant pursuit of quality, function, safety and good service, we have developed into a leading supplier in the field of autoclaves.

We are aware that you expect optimal product quality and product reliability from us. Through our experience and high quality standards, we ensure that we meet these requirements. The autoclave you purchase is manufactured under a certified quality management system in accordance with ISO 13485 and is monitored annually by TÜV SÜD in audits lasting several days.

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1 General information

Please read and understand this manual before using the sterilization paper sealer. The device may only be used for its intended purpose; any other use is not permitted. The device may only be dismantled or assembled by appropriately trained specialists. During installation and use, all safety instructions, nameplates and stickers must be completely retained.

1.1 Symbol description

Symbol	Description
	Indicates a dangerous situation that, if not observed, can have mild to life-threatening consequences.
	Indicates a situation that, if not observed, can lead to damage to the device.
	Indicates an important piece of information

1.2 Disposal

Before decommissioning the sealing device, ensure that the device is completely disconnected from the power supply. Unplug and remove all cables. Empty the device of any remaining rolls, foils or other accessories.

The sealing device must not be disposed of with household waste because it contains electronic components. Take the device to an authorized dealer, manufacturer or municipal collection point for WEEE to ensure proper and environmentally sound disposal.

1.3 Manufacturer



Durchlauf-Siegelgerät
Continuous band sealer

Modell / Model	CertoSeal 200	Max. Temp.	220°C
Spannung / Voltage	220V -240V 50Hz	Gewicht / Weight	16kg
Leistung / Power	500W	S./N.	CS2000001
Prod. Datum / Date	2025	Artikel Nr. /Article No.	8501926
Hersteller / Manufacturer	CertoClav Sterilizer GmbH Peintner Str. 10, 4060 Leonding, Austria		



Durchlauf-Siegelgerät
Continuous band sealer

Modell / Model	CertoSeal 300	Max. Temp.	220°C
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1.4 Declaration

Rev.: 0 / Date: 02.09.2025

Manufacturer: CertoClav Sterilizer GmbH

Address: Peintner Str. 10, 4060 Leonding, Austria

Product: Continuous sealing device

Produktnamen: CertoSeal 200, CertoSeal 300

Main standards applied /

EN ISO 11607-2

EN 61010-1/-2-010

EN 61326-1

EN IEC 63000

We hereby declare, under our sole responsibility, that the product listed above complies with the requirements of the following directives as well as their implementation into national laws.

2006/42/EC (Machinery Directive)

Conformity assessment procedure

Directive 2006/42/EC Annex VIII

2014/35/EU (Low Voltage Directive), 2014/30/EU (EMC Directive) and 2011/65/EU (RoHS Directive)

The conformity assessment was carried out under the sole responsibility of the manufacturer.

Leonding, 02.09.2025



Michael Simon
Manager

2 Safety

Before switching on, make sure that there are no sources of danger, such as a damaged power cord, a defective display or a deformed housing. During operation, pay attention to irregularities such as unusual noises, smoke, odors or an uneven speed. In such cases, the operation should be stopped immediately and the power supply should be cut off to check the cause. If an error message appears, follow their instructions or contact customer service immediately. Use in areas with a potential risk of explosion is strictly prohibited. Before each cleaning, the power supply must be disconnected.

	When inserting the bags for sealing, care must be taken to ensure that there are no objects to be sterilized in the welding machine itself.
	The power cord must be kept away from frequently moved or displaced objects.
	Before each transport or relocation of the welding machine, the power cord must be disconnected.
	The path of the sterile bag must not be blocked by other objects.
	The back of the welding machine must be placed at least 5 cm away from walls or other equipment so as not to block the air outlets.
	Before sealing, it must be ensured that the set welding temperature is reached.
	Liquids must not get inside the appliance under any circumstances.
	Fans and vents must not be covered or blocked.
	Regularly remove dust from the bottom of the appliance as well as from the installation surface.
	Warning sign (W022) Warning of sharp object - according to DIN EN ISO 7010.

3 Device Description

3.1 Intended use

The sealing device is intended for professional use in the medical field, especially in clinics as well as medical and dental practices. It is used for reliable heat sealing of surgical and medical instruments in sterilization rolls, ensuring safe sterilization and subsequent storage. The CertoSeal 300 continuous sealing device is not considered a medical device within the meaning of the Medical Devices Regulation. Any use outside the described purpose is not permitted.

3.2 Scope of delivery

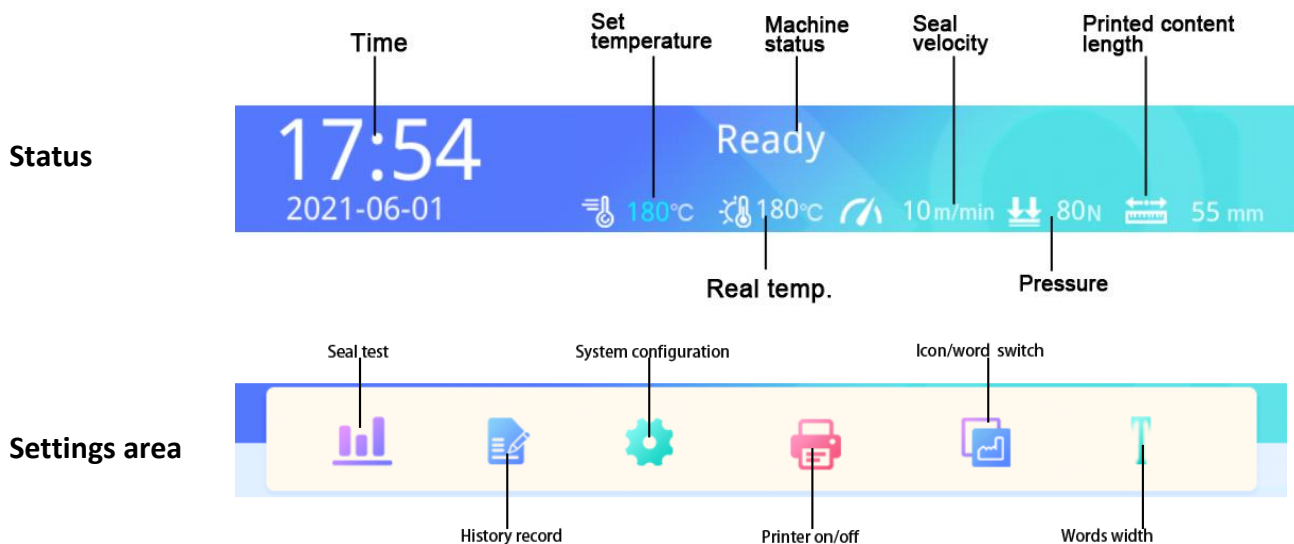
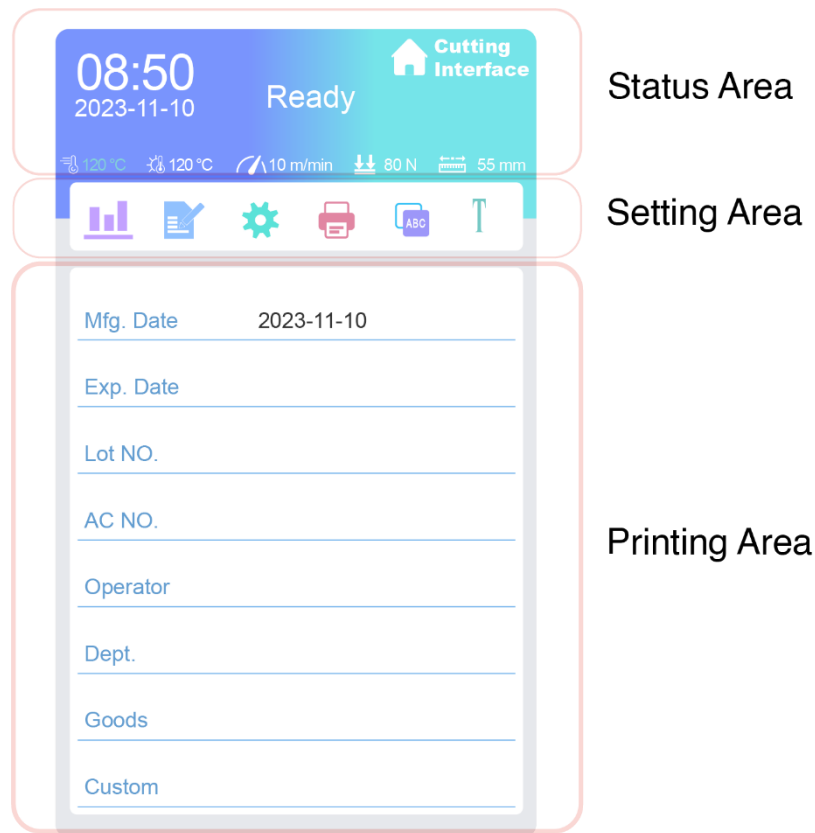
Please check the scope of delivery before using the device.

- Continuous sealing device
- User manual with declaration of conformity
- Power cord
- Stainless steel base table

3.3 Symbol designations

Symbol	Designation
	Manufacture
	Expiration date
	Batch number
	Autoclave number
	Operator
	Department
	Object
	More content
	Warning sign (W022) Warning of sharp object - according to DIN EN ISO 7010.

3.4 Touch-Display



3.5 Functionality

The medical sealer works with a fast, automatic continuous heat sealing technique to improve the efficiency of the sealing process. It is equipped with a 7-inch color touchscreen that matches daily operating habits and allows intuitive control.

The machine has an intelligent temperature control system that can be adjusted from room temperature to 220°C, keeping the working temperature accurate at $\pm 1^\circ\text{C}$. When the set temperature is reached, both graphic and acoustic cues are given. If the upper temperature limit is exceeded, the protection mode is activated, the device stops automatically and emits a warning sound. In addition, the standby temperature and time can be adjusted, so that the machine maintains the desired temperature when inactive.

During operation, the device continuously monitors its condition and has error messages and alarm functions to detect faults at an early stage. The sealing seam width is ≥ 12 mm, and the sealing thickness meets the requirements of the standard for validatable sealing devices valid in Germany, Austria and Switzerland.

The device is also equipped with a USB port: English letters, numbers, symbols and special characters can be printed on sterilization bags. This makes it possible to meet, for example, the expiration date, batch number, operator information and other requirements of the Ministry of Health. The width of the printed font is adjustable ("narrow", "normal" or "wide") and can be adapted to the size of the sterilization bags. A notice when the print length is exceeded prevents content from being cut off.

The printing belt can be conveniently dispensed from the side, so that it can be replaced without moving the machine. The machine uses ceramic heating plates, which provide fast, uniform heating and allow dry heat to be applied, ensuring a long service life.

4 First commissioning

Removal from the packaging

1. Open the transport packaging carefully.
2. Take the device out carefully.
3. Check the device for damage in transit.

4.1 Installation conditions

**Caution**

Failure to comply with the installation conditions may result in injury, malfunction or damage to the device.

- The device must not be operated in potentially explosive atmospheres.
- It is intended for indoor use only.
- It is intended to be used outside the patient environment; the distance to the treatment place should be at least 1.5 m.
- Place the device in a dry, dust-protected place.
- Make sure there is enough distance from walls or other surfaces to ensure adequate ventilation.
- Avoid direct sunlight and keep the device away from other heat sources.
- Make sure the device is protected from shocks and vibrations.

4.2 Device connection

**Caution**

Follow the instructions to ensure a smooth and safe process.

- Observe the regulations and connection conditions of your electricity supplier.
- Do not operate the appliance if the power cord or plug is damaged.
- Do not alter or damage the power cord or power plug.
- Do not bend or twist the power cord.
- Never pull the cord to remove the plug from the outlet; always reach directly to the mains plug.
- Make sure that the power cord is not pinched.
- Do not place heavy objects on the power cord.
- Do not run the power cord near heat sources.
- Do not fix the power cord with sharp objects.
- The mains socket must be freely accessible after installation so that the appliance can be disconnected from the mains at any time by unplugging the mains plug if necessary

4.3 Device

Printer area (Optional as order configuration)

Click on the items to be printed to control whether or not their contents are printed on the bag. Light blue mark means that the item is being printed, gray mark means that it will not be printed.

Mfg. Date	2023-11-10
Exp. Date	
Lot NO.	
AC NO.	
Operator	
Dept.	
Goods	
Custom	

Click on the right pane of each item you want to print to edit the contents.

 Back

Scalpel	☒		☒
Tweezers	☒		☒
Forceps	☒		☒
	☒		☒
	☒		☒
	☒		☒

Select confirmPrevious 1/5 Next

System

1. Select Ready Temperature

Click on "Standby Temperature" to select the temperature from the drop-down menu: "Room Temperature", "60 °C", "80 °C" or "120 °C".

2. Set standby time

Click Standby Time to select the time from the drop-down menu: Off, 10 min, 20 min, or 30 min. If no operation is maintained during the standby time, the sealing machine maintains the selected standby temperature.

3. Cooling Temperature

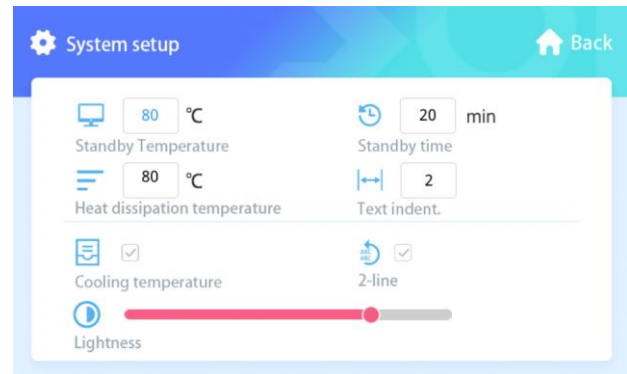
The cooling temperature controls the turning on and off of the fan according to the set temperature.

4. Text indent

An indentation length of 1, 2, 3 or 4 characters can be selected. The text feeder is only effective if the printer option has been ordered.

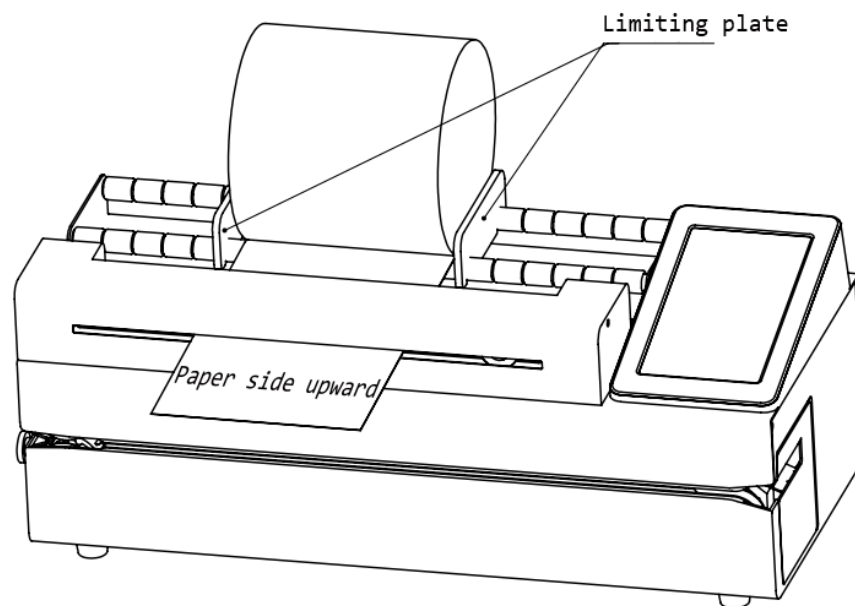
5. Two-line (2-line)

When activated, two lines of content can be printed on the bag; otherwise, only one line will be printed. Single-line or two-line printing is only effective if the printer option has been ordered.



4.4 Insertion of sterilization rollers

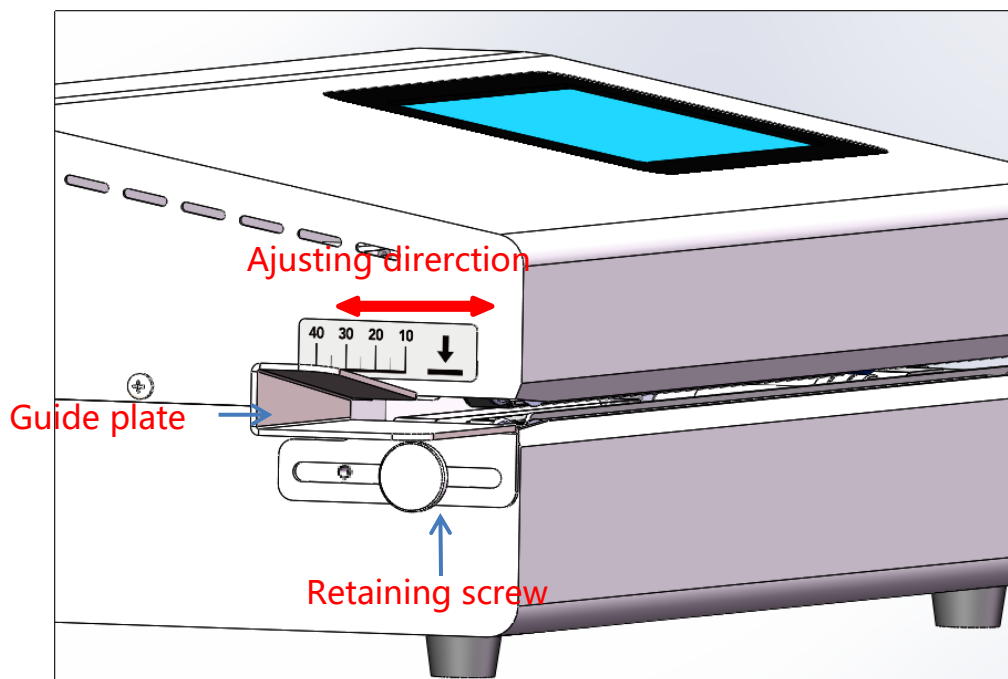
According to WS310.1 (Central Sterile Supply Department Part 1: Management Standard), suitable bags made of paper or paper-plastic that meet the requirements must be selected. Before use, check that the markings printed on both sides of the bags are clearly and sufficiently visible.



1. Place the sterilizer roller on the slicer's grab bars, paper side down.
2. Pull out 10cm from the end of the roll and insert the end of the roll into the cutter. Use the insertion gap under the metal sheet.
3. Place the two boundary plates on the grab bars on the two sides of the roll (order option).

5 Sealing process

5.1 Adjust the distance of the sealing seam to the packaging edge



The guide plate is placed on the left side of the device. Loosen the thumbscrew under the guide plate by turning it counterclockwise and adjust the guide plate horizontally according to the distance to the edge. Once positioned, tighten the thumbscrew again.

For the instruments to be sterilized, choose sterilization bags of suitable width and length. Deactivate the printer (printer is optional) and the "Lot No. increase" and seal one end of the sterilization bag. Then place the instruments in the bag. According to national regulations, the distance between the end of the instruments and the sealing seam in the sterilization bag must be greater than 2.5 cm. Therefore, make sure to use sufficiently long bags.

5.2 Sealing process

Sealing must only take place when the set sealing temperature has been completely reached (pay attention to the display in the status area). If the sealer does not automatically feed the paper, the sealing temperature has not yet been reached.

With automatic feeding, make sure that no small parts (e.g. from instruments) are fed together with the sterilization packaging. Such parts can damage both the transport mechanism of the device and the sterilized goods and packaging. In this case, the warranty and guarantee are void.

Use only the packaging materials specified in the user manual. Other materials must not be passed through the device.



It is recommended to insert the slide side up into the device. The packaging is automatically detected and pulled in independently.

Preparing the packaging

1. Click on **Cutting Interface**
2. **Press Forward (Feed)** to feed the roll.
3. **Press** and hold Return to return the retracted roll.
4. Enter the length (minimum 80 mm) and quantity for each task. Activate the respective task by marking it.
5. Click **Start** to perform the selected tasks in order.

After a cutting process is complete, the device stops and waits for the next cut.

Task	Length	Qty.	Current Qty.	Activate
1	80	10		☒
2	200	20		☒
3				☐
4				☐
5				☐
6				☐

6. After sealing one end, insert the instruments into the bag. Fill pointed or irregularly shaped objects only with protection. Choose the bag size appropriately and do not overfill (fill level < 75%) to avoid damage and uneven sealing seams.
7. Insert the bag with the paper side down and the foil side up to the guide plate. The device transports the bags automatically.
8. If the guide piece is not available: Hold the bag opening flat, insert it parallel to the front of the device and hold it in place throughout the sealing process.



6 Maintenance

6.1 Routine activities, maintenance and validation

For the safe routine operation of sealing devices in general, regular tests of the sealing seam must be carried out. A distinction is made between daily, weekly and annual checks. In most federal states of Germany and cantons in Switzerland, initial validation is also required before the first commissioning.

How often	Description
Daily before the start of the practice	At the beginning of each working day, a test seal seam must be prepared and checked both visually and mechanically. Visual inspection: The sealing seam must be uniform and complete, without wrinkles or imperfections. In addition, it should match the color of the factory sealing seam (industrial seam) at the edge. Peel test: When opening (peeling), the paper must be able to be removed from the film almost without leaving any residue. Tensile strength verification: The force applied when opening the sealing seam must be comparable to the force required to open the factory sealing seam.
Weekly	Once a week, the sealing seam must also be visually checked with the help of suitable test aids (e.g. Seal Check). The result of this inspection must be documented.
Annual	Maintenance: Maintenance is required every 30,000 cycles (batches) or at the latest every 24 months. In addition, the sealing device must be serviced once a year. To schedule a service appointment, please visit www.steri24.de or conclude an attractive maintenance contract with Steri24. Validation: The sealing device can be validated and must be revalidated annually in most federal states (DE) and cantons (CH) for use in the instrument reprocessing of semi-critical and critical instruments. Part of the validation is also the seal strength test in accordance with DIN EN 868-5. Make an appointment for this on www.steri24.de or conclude an attractive validation contract with Steri24.

7 Malfunctions

As a general rule, if anything is unclear or there is a risk of damage, the manufacturer should be contacted immediately.

CertoClav Sterilizer GmbHPeintner Str. 10

4060 Leonding

AT

Phone: [+43 732 674 278](tel:+43732674278)

Email: support@certoclav.com

There are sensors and high-temperature elements in this device. Dismantling the machine without instructions is prohibited.

8 Specifications

Model	CertoSeal 300 und CertoSeal 200
Dimensions	540 x 235 x 215mm
Weight	16 kg
Achievement	400W
Case	Coated Carbon Steel
Sealing temperature	Adjustable from room temperature to 220°C
Heating speed	Rises to 180°C in 40 seconds
Sealing seam width	12mm
Cutting speed	≥ 10 m/min
Border	0–40 mm
Cutting speed	≥ 15 m/min
Cutting width	0–330 mm
Control panel	7-inch touchscreen
Printer	Yes

9 Transport and storage

- Transport the device only in its original packaging or in suitable protective packaging to avoid shock, vibration and moisture.
- Store the device in a dry, dust-protected place and keep it away from direct sunlight, heat sources and moisture.
- Make sure that the device does not tip over or be stored on its sides; It should always stand upright.
- The ambient temperature for storage and transport should be between 5 °C and 40 °C to maintain functionality.