

# Pharmaceutical Autoclaves



Pharmaceutical Autoclaves for Pharmaceutical Production



Pharma Line

# Pharmaceutical Autoclaves

Tuttnauer pharmaceutical autoclaves are designed and manufactured in a state of the art facility in compliance with cGMP regulations to meet the technical challenges of pharma and biotech industries. Tuttnauer autoclaves provide precise control and reliable sterile processing and pasteurization.

Tuttnauer is a leading manufacturer of infection control solutions for the Life Science industry with decades of experience and 350,000 installations worldwide including Pharma Facilities, Research Institutes, Laboratories, Hospitals & Clinics.

Tuttnauer autoclaves are customized to meet customer requirements for the pharma industry.

- Post-production Terminal sterilization
- Pre-production sterilization
- Laboratory and R&D
- Quality Control (QC) applications
- Biohazard waste sterilization

Tuttnauer manufacturers autoclaves made from long lasting materials and reliable components, supported with expert after-sales technical service to satisfy customer expectations.



## Pharmaceutical Line

### Innovation for Customization

With over 90 years of manufacturing experience we have striven for excellence in design to ensure our products are up-to-date with state-of-the-art technology. Our strong engineering ability gives us a competitive edge for customizing our products to meet customer budget and requirements, including:

- Autoclaves designed to layout limitations
- Specific customer design requirements
- Optimal chamber loading design
- Custom program cycles

## Precision Manufacturing & Automation

Tuttnauer's manufacturing process and equipment are constantly updated to be at the forefront of modern automated manufacturing. To ensure uniform manufacturing results and precision-made sterilization equipment Tuttnauer uses high-tech industrial processes including laser cutting, robotic bending, robotic polishing, and automated welding. Our customers receive autoclaves that are robust, reliable and provide precise and consistent results.

## Inside Every Tuttnauer Autoclave is a Premium Pressure Vessel

Tuttnauer autoclaves are equipped with robust ASME and PED compliant chambers as large as 17,000 liters. Customers often require custom chamber sizes and Tuttnauer's wide range of chamber configurations provide precisely what is needed without compromising chamber design quality and surface finish.

## Sophisticated Control

The advanced user-friendly Allen-Bradley control system gives the operator precise and reliable control of all autoclave operations. The PLC features sophisticated custom cycles, cycle simulation, detailed cycle data recording, file transfer ability, and connections to SCADA and WiFi devices. The PLC is 21 CFR part 11 validated.

## Documentation & QA

We provide our customers with full documentation from the initial user specification (URS) to installation and SAT validation. Thorough testing and QA ensures that we supply top-quality autoclaves that meet the customer's specifications.

## Quality Components

Tuttnauer uses top-quality standardized industry components from leading manufacturer's available worldwide. Customers have the opportunity to source parts from local suppliers which saves time and lowers operational costs. Tuttnauer is also committed to supplying parts and supporting our customers.

## Reliable and Consistent Processing

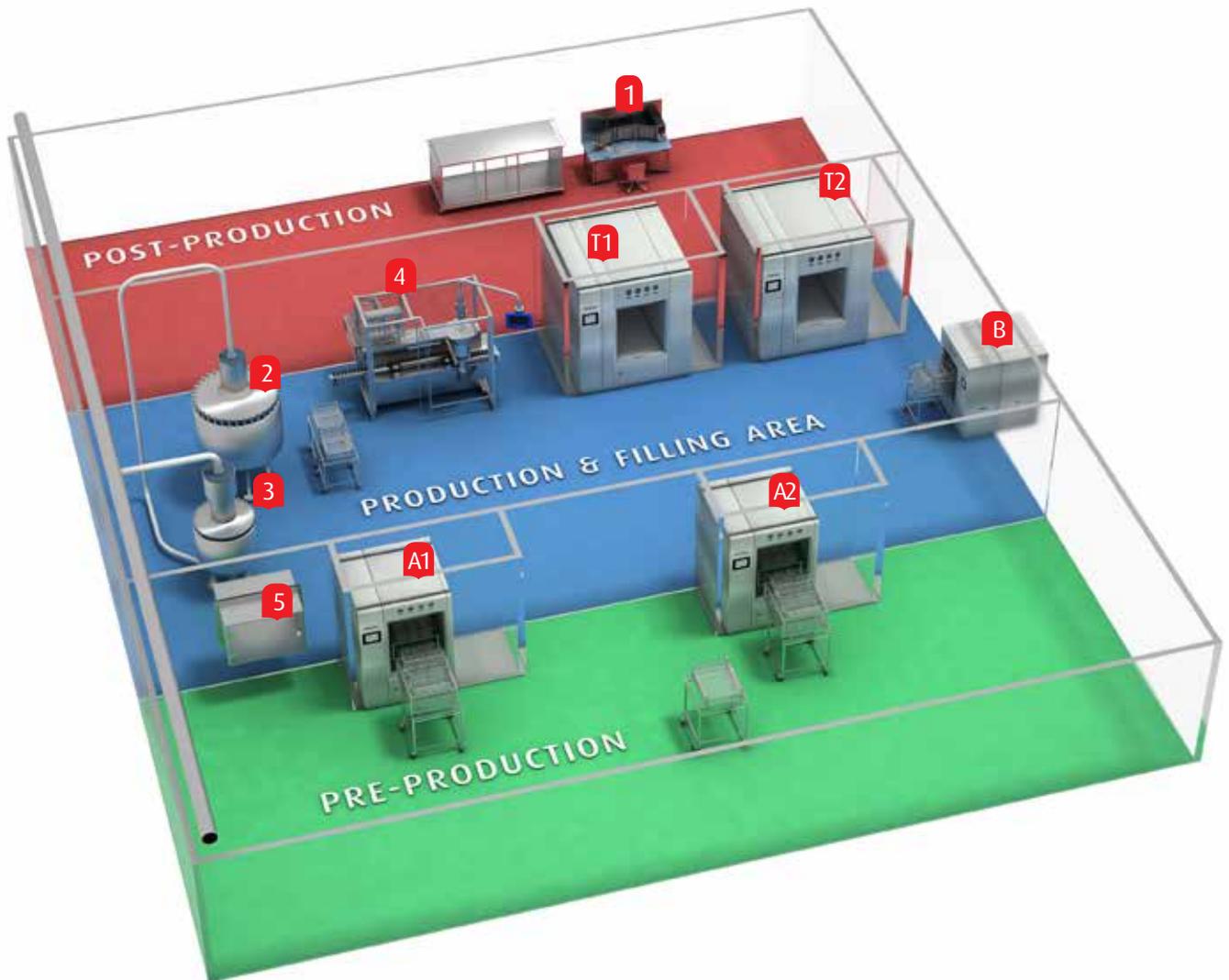
The combination of automated precision manufacturing, adherence to cGMP regulations, quality components and sophisticated cycle control ensures that your loads will be reliably and consistently sterilized with every cycle.



## Autoclave Applications in Pharmaceutical Facilities

In the Pharmaceutical/Biopharmaceutical industry Tuttnauer offers a wide range of autoclaves:

Over Pressure - Air Steam Mixture & Hot Water Spray • Gravity Displacement • Prevacuum • Biohazard



### Pre-Production

- A1. Pure Steam Sterilizer (Hard Loads)
- A2. Pure Steam Sterilizer (Liquid Loads)
- 5. Pass-through Window

### Production & Filling Area

- 2. Reactor 1
- 3. Reactor 2
- 4. Filling Machine
- T2. Over-Pressure Sterilizer (Bulk Capacity)
- T1. Pure Steam Sterilizer (Bulk Capacity)
- B. Biohazard Sterilizer

### Post-Production

- 1. Control Station

## Pure Steam Sterilization

**Pre-production** processing involves the sterilization of materials, equipment, containers and other items entering the production floor.

**Post-production** sterilizers are used for terminal sterilization of finished goods.

**Laboratory applications** have a broad scope mainly R&D (product development, manufacturing process development, packaging selection) and Quality Control (QC).

### Pre & Post Vacuum

Pre-vacuum removes air trapped in loads such as garments and hollow loads to achieve effective steam penetration. Post-vacuum assists in quick drying to reduce sterilization cycle times. Ideal for hard and porous loads.

### Gravity Displacement

Sterilization is achieved when steam enters the chamber and displaces the air, ideal for liquid loads.

Common Applications		Common Program Cycles	Common Optional Features
<b>Solid Loads</b>	Machine Parts Empty glassware Stainless steel parts / vessels	<b>Pre &amp; Post Vacuum</b> Unwrapped solid Wrapped Porous	Air Detector (hard and porous) Steam Quality Check Sanitary Filter Automatic Water Intrusion Test Multipurpose Valve Bio-shield Jacket cooling (liquid loads) Steam Generator
<b>Porous Loads</b>	Textile Filters (ATF process) Rubber stoppers Cleaning aids Tubing	<b>Gravity</b> Liquid (open) Liquid (sealed)	
<b>Liquid Non-Sealed</b>	Beakers Bottles	<b>Test Cycles</b> Leak Bowie & Dick Filter sterilization	

## Over Pressure Sterilization

Over pressure sterilization is a precisely controlled process ideal for terminal sterilization of soft packaged items especially sealed liquids, parenteral and ophthalmic products.

**Air Steam Mixture (ASM)** - Sterilization is achieved by circulating a mixture of Air & Steam in the chamber ideal for small sized delicate product packaging.

**Hot Water Spray (HWS)** - Sterilization is achieved by circulating hot water over the load.

Common Applications	Common Program Cycles	Common Optional Features
Sealed Liquid Sealed Ampoule/Vials Sealed IV Bags/bottles Pre-Filled Syringe (PFS) Sealed Contact Lenses	Liquids (sealed) Ampoule Leak Detection <b>ASM Cycles</b> Air Steam Mixture Filter Sterilization <b>HWS Cycles</b> Hot Water Spray Cleaning-In-Place (CIP)	<b>Bio-shield</b> <b>ASM Features</b> Steam quality check Jacket cooling system <b>HWS Features</b> In-chamber sprinkling system Water circulation pump

## Biohazard Waste Sterilization

Tuttner's bio-hazard sterilizers decontaminate dangerous pathogens prior to disposal. Tuttner provides autoclaves suitable for biosafety (BSL) applications. The autoclaves are based on pure steam sterilization.

Common Applications	Common Program Cycles	Common Optional Features
<b>Biohazard</b> Biological Waste Disposal	Biohazard liquid Biohazard solid	Thermal Biohazard Biohazard Filter Blow-off Tank Bio-shield

## Support for Your Investment

Tuttnauer is dedicated to supporting our customers from pre-sales and installation to production.

We understand the time and financial investment made by our customers and provide a team of experienced support managers and expert engineers needed to make your project installation and validation successful.

Support is provided throughout every stage of the development, purchase, manufacturing, delivery and installation process. Tuttnauer's team invests great effort into understanding your requirement specification and transforms it into high-end autoclaves. We provide full support to our clients during the installation and validation of our machines at their facility.

**We provide safe autoclaves that conform to cGMP regulations and are operationally reliable thereby enabling continuity of a pharma facilities' production workflow.**

### Pre-Sales

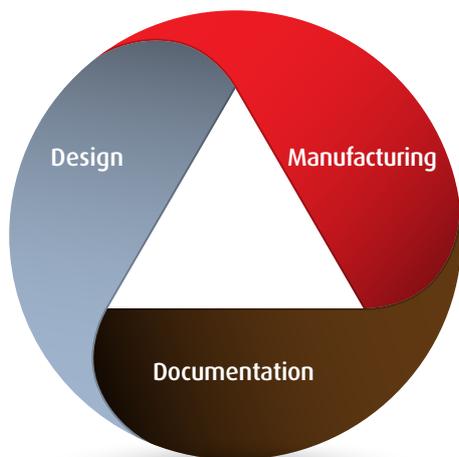
We assist customers in defining the optimal sterilization solutions based on:

- Load type and size
- Required cycles
- Space limitation
- Delivery time
- Budget



### Manufacturing

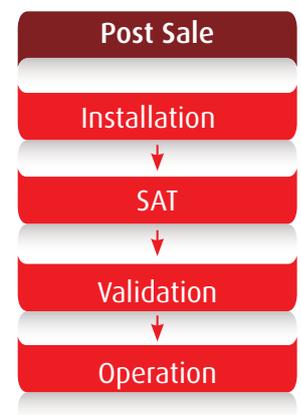
The manufacturing process is fully documented according to detailed design and quality considerations. Factory Acceptance Testing (FAT) ensures that the product leaves the factory in compliance with the customer's requirements.



### Post-Delivery

Tuttnauer's team is available to assist during autoclave installation and connection to utilities. During Site-Acceptance Testing (SAT) our support also includes assistance with calibration and validation.

Additional help is available regarding PQ, Training & Operation.



## Adherence to the cGMP Regulations

### Specification, Documentation & Acceptance Testing

To ensure that our pharma autoclaves satisfy your requirements we implement a strict documentation and qualification process according to cGMP regulations. This process starts with defining specifications and expectations which will impact every aspect of manufacturing.

#### Deliverable Documentation

Our cGMP documentation process is an integral part of each stage of the project management and manufacturing process. The following is a partial list of documentation that we provide:

#### Order Related Documentation

- URS and Compliance
- Commercial Order Documentation

#### Design Qualification (DQ)

- Pressure vessel design (ASME/PED)
- Layout drawing
- General drawing
- Piping and Pneumatic drawing
- Electrical drawings
- Accessories drawings
- Software Requirements Specification (SRS)

#### Installation Qualification (IQ)

- Chamber radiology testing
- ASME/PED certificate
- Surface finish reports
- List of materials and components (with ID tagging)
- Sanitary piping and component certificates
- Datasheets
- Orbital welding video reports
- P&ID

#### Operation Qualification (OQ)

- Certification of calibration
- Validation and test reports

#### Manuals

- Installation instruction
- Operation manual
- Maintenance manual
- Technical manual

#### Acceptance Testing

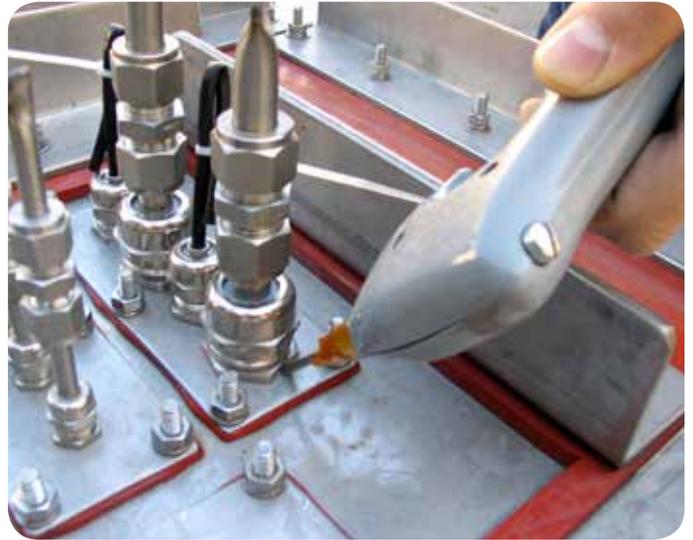
Each autoclave is subjected to a strict examination in Tuttnauer's advanced testing laboratory. Following our internal testing, we invite the customer to conduct a Factory Acceptance Testing (FAT) which includes DQ, IQ, OQ review. In order to facilitate site validation, Tuttnauer provides a Site Acceptance Testing (SAT) service which includes review of documentation, installation and operation of the autoclave.





### Chamber and Jacket Construction

The inner walls of the 316L stainless steel chamber have a surface level polish less than  $0.6\ \mu\text{m}$  [SF6] (specific custom polishing values less than  $0.4\ \mu\text{m}$  [SF4] are available upon request). The chamber is constructed to be drainable with smooth, rounded and sloped surfaces to enable proper drainage and cleaning. The chamber is fully jacketed.



### Biological Seal (bio-shield )

The bio-shield provides a hermetic seal for maximum biological containment between the differently qualified zones. It is constructed from stainless steel plates and flexible neoprene insulation to prevent micro-organisms from passing between zones. The bio-shield includes a jacket frame and wall frame.



### Sanitary Piping

Full sanitary primary piping with tri-clamp connectors, orbital welding and sanitary level components. Tuttnauer sanitary piping is designed and constructed in accordance with cGMP requirements. Our sanitary piping's allows full drain ability to minimize risk of contamination.



### Sanitary Air Filter

Following the sterilization stage a  $0.2\ \mu\text{m}$  air filter ensures that bacteria free air enters the chamber. The sanitary filter can be sterilized-in-place (SIP). The filter housing is designed with ports for filter integrity testing.

## Features and Options

Pressure Vessel	Standard	Optional
A wide range of chamber sizes (160 to 17000 liters) are available to meet customer needs.		
AISI 316L stainless steel chamber	✓	
AISI 316Ti stainless steel chamber		○
Internal chamber surface polish <0.6 Micro Ra.	✓	
Internal chamber surface polish up to 0.2 Micro Ra.		○
Electropolish (chambers less than 1300 liters)	✓	
Electropolish (Bulk chambers > 1300 liters)		○
Jacket: Stainless Steel 304	✓	
Jacket: Stainless Steel 316L / 316Ti		○
Stainless steel bottom frame	✓	
Jacket cooling system (for liquid load sterilizers)	✓	
Air operated gasket	✓	
FDA approved sealing materials	✓	
Insulation: Mineral free rock wool	✓	
Insulation: Foniteck		○
Air Steam Mixture (ASM)		○
Hot Water Shower (HWS)		○
Cleaning-in-Place (CIP)		○
Cabinet		○
Bio-Shield Frame (BSL 1-2)		○
Bio-Shield System (BSL 3-4)		○
Seismic-Tie-Down (STD)		○

Control System	Standard	Optional
Allen-Bradley Control System	✓	
English language operating system	✓	
5 Level password security system	✓	
Graphical display of Temperature and Pressure trend charts	✓	○ <sup>2</sup>
7" Advanced user-friendly touch screen control system	✓	
15" Advanced user-friendly touch screen control system		○
Built-in printer with full record of cycle data	✓	○ <sup>3</sup>
Chart Recorder		○
SCADA		○
Barcode Reader		○

<sup>2</sup> Additional languages are available

<sup>3</sup> Various upgrade options are available

Piping and Components	Standard	Optional
<b>Primary:</b> Full Sanitary Piping	✓	
<b>Primary:</b> Simplified Sanitary Piping		○
<b>Secondary:</b> Stainless Steel piping & components with Tri-clamp connectors	✓	
Sanitary Air Filter (0.003 µm) in stainless steel housing (PALL)	✓	
Powerful Speck water ring vacuum pump	✓	
4 point temperature sensors	✓	
4 point pressure sensors	✓	
2 Flexible PT 100 (in chamber)	✓	○ <sup>1</sup>
2 Validation ports <sup>1</sup>	✓	○ <sup>1</sup>
Absolute Pressure Gauge		○
Air Detector		○
Steam Quality Test		○
Multipurpose Valve		○
Water Recycling System		○
Automatic Filter Water Intrusion Test (WIT)		○
Biohazard Thermal Sterilization		○
Biohazard Exhaust Filtration		○

<sup>1</sup> More are available upon request.

Validation and Support Document	Standard	Optional
DQ/IQ/OQ	✓	
P&ID	✓	
500	✓	
21 CFR part 11	✓	
Orbital welding reports	✓	
Software Sequence of Operation (SSO)	✓	
FAT/SAT Protocol		○



## Advanced Control System

Take advantage of Tuttnauer's sophisticated user-friendly PLC control system based on the advanced Allen-Bradley MicroLogix 1400 platform in all pharmaceutical autoclaves.

### Standard Features

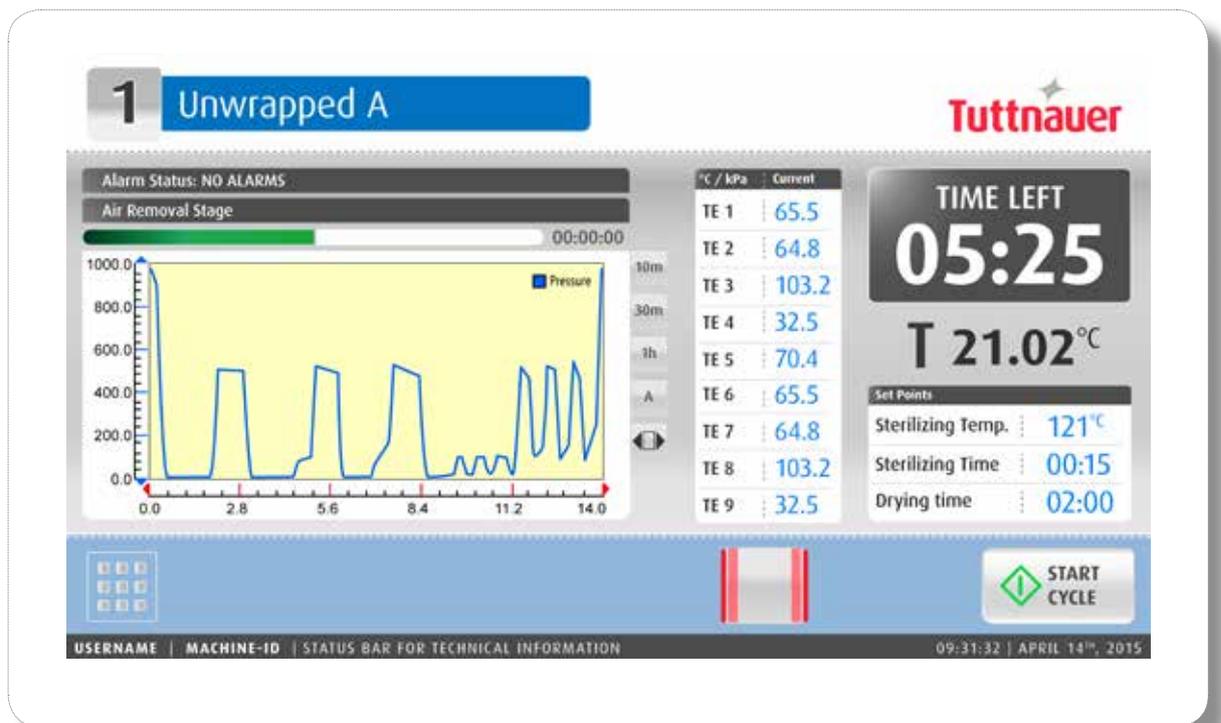
- 7" Multi-color touch screen (loading and unloading side)
- Sterilization temperature range 110°C to 137°C
- 5 Operation access levels and up to 99 user accounts
- Over 1000 cycles & event data stored in internal memory (HTML and CSV)
- Up to 100 cycle programs (customizable by user)
- Cycle simulation (for testing cycles)
- Easy file transfer via USB or LAN
- Thermal serial printer
- Ethernet connection for remote monitoring, maintenance, and software updates
- Preventative maintenance notifications based on the number of cycles
- In/Out test
- 21 CFR part 11

### Optional Features

- 15" Multi-color touch screen (loading and unloading side)
- Independent sensors for reference or monitoring
- SCADA
- Chart recorder
- UPS
- Screen View & Control with tablet/mobile phone via LAN/WiFi connection
- Real-time piping diagram (15" screen only)
- Barcode integration
- F<sub>0</sub> software calculation
- Custom cycle program design according to user needs

### HMI Screen

- On screen display of historical cycle data (CSV format)
- Graphical display of Temperature and Pressure trend graphs
- Multi-color display for easy reading
- Quick access to important information
- Multilingual support for over 20 languages





Standard	—
Optional	—

# P.L.C

AB CONTROLLER



Standard Printer



Touch Panel 15"



Touch Screen 7"



Paperless



Paper Chart Recorder



SCADA Software



Remote Control\*

Enables external remote access for technical support

\*For remote control operation with the Tablet option, a WiFi router is required.



## Accessories

To assist our customers in fully utilizing our solutions, Tuttnauer offers customized accessories.

### Loading Equipment

Optimal load placement inside an autoclave promotes full utilization of chamber capacity while maintaining operator's ease-of-use. Our loading equipment includes:

#### Automatic Loading

Tuttnauer's pharmaceutical autoclaves can be designed to integrate with automated loading and unloading systems.

#### Loading Carts and Transfer Carriages

The 316L loading carts are designed to roll from the transfer carriage onto the chamber rails. Tuttnauer's unique chamber rails are fully removable and cleanable without any screws or threads. Loading carts have configurable shelves customized to meet customer needs and accommodate multiple loads & sizes in a single cart. To ensure safety and ease-of-use the carriage is equipped with a lock preventing sliding of the cart as well as swivel wheels with wheel breaks.

#### Internal Shelves and Baskets

For smaller size autoclaves, mainly used in R&D and QC, internal built in shelves and baskets provide maximum utilization of laboratory space.



#### Fully custom cart design for ATF filters.

Tuttnauer develops custom carts to accommodate unique loads and safe transportation of loads.



### Loading Cart Custom Configurations

During the Pre-Sales process Tuttnauer's engineers consult with customers to develop loading equipment based on intended load and facility limitations.

Various considerations are taken into account when designing loading equipment including:

- Load type and size
- Number of loads per cycle
- Number of cycles per day
- Load orientation and position in cart
- Autoclave chamber dimensions
- Factory layout limitations

### Steam Generators

For customers without clean steam utilities at the intended autoclave site, Tuttnauer provides built-in and standalone steam generators with a power range from 18 kW to 72 kW:

- **Electrical Steam Generators** use electricity as the energy source to generate steam
- **Steam to Steam Generators** use available steam as the energy source to generate clean steam

Our cGMP pure steam generators are made of 316L stainless steel with stainless steel components and tri-clamp connectors.

## Components and Parts

Tuttnauer autoclaves use components and parts made by internationally renowned manufacturers, freeing the customer from having to buy expensive “custom-made” parts. Using industry standard components ensures reliability, eases maintenance and reduces total cost of ownership.

Tuttnauer assists customers regarding which components and spare parts to keep in inventory and we provide support regarding their use and installation.

Tuttnauer commits to maintain stock of components for maintenance and replacement. Our dedicated web portal is available to customers and provides detailed parts information to help source components locally.

In cases where customers have a specific preference for a component manufacturer, Tuttnauer engineers will accommodate the request and design the machine with the specific components.

Some of the components found in Tuttnauer autoclaves are made by the following world class manufacturers:



## Standards and Directives

Tuttnauer manufactures autoclaves according to Pharmaceutical standards/directives required by our customers. The following is a partial list of the standards and directives supported by Tuttnauer:

### Quality Standards

- cGMP
- ISO 9001:2008 - Quality Management Systems
- EN ISO 13485:2012 Quality Management System – Medical Devices

### Directives

- PED 97/23/EC - Pressure Equipment Directive
- 2002/96/EC WEEE and 2002/95/EC RoHS
- 2006/42/EC Machinery directive
- 6002/59/EC Electrical equipment
- 2004/108/EC Electromagnetic compatibility
- GAMP

### Technical Standards

- DIN 58950-2:2011 Steam sterilizers for pharmaceutical products
- ASME Code section I and section VIII. Div.I
- ASME BPE2009 for Pharma
- EN 285: 2006+A2: 2009 Large steam sterilizer
- ANSI \ AAMI – ST 8: 2008 Hospital steam sterilizers
- IEC 61010-1: 2010 Safety Requirements for measurement control and laboratory use
- IEC 61010-2-40: 2005 Safety requirements for sterilizers used to treat medical materials
- EN 61326-1: 2006 Electrical Equipment for EMC requirements
- EN 17665-1: 2006 Sterilization of health care products – moist heat
- EN 554 Validation and routine control
- In compliance with FDA QSR 21 CFR part 820 & part 11

## Safety

### for Personnel, Autoclave, Load

Safety of personnel, autoclave and load are priority in the design, construction and operation of any Tuttnauer autoclave. Tuttnauer is committed to the highest industry safety standards and directives to ensure safety not only for your employees operating the autoclaves but also for the production facility and loads being sterilized.

Tuttnauer autoclaves are provided with redundant independent monitoring systems and audiovisual alarms to notify operators of any issue that requires attention. Emergency stop buttons on both sides of the autoclave may be used to stop the autoclave cycle.

### Door Safety

Autoclave doors are designed with redundant mechanisms to ensure operator safety, including:

- Door on clean side will not open until after chamber sterilization
- On double door autoclaves only one door can be open at a time
- Door will not open when chamber is pressurized or above a specified end-temperature
- Cycle will not start and steam will not enter chamber when door is open
- Door status is displayed on display(s)



### Electrical Safety

Autoclaves comply with IEC 61010-1 and IEC 61010-2-40 (Safety requirements for sterilizers used to treat medical materials)

- Proper electrical grounding (to earth)
- Short circuit protection
- Circuit breaker
- Emergency stop switch

### Safety Pressure

Chamber pressure vessel is ASME or PED certified and approved. All ASME certified autoclaves are inspected by an independent authorized inspector. The jacket and chamber are equipped with pressure release valves.

### Thermal Safety

To ensure operator safety hot surfaces are covered with thermal insulation and cautionary safety labels are provided.

## Your Sterilization & Infection Control Partners

Tuttnauer is an autoclave manufacturer, plasma sterilizer manufacturer and provider of washer disinfectors and other infection control products in the Life Science and Healthcare industries. For over 90 years Tuttnauer has been an industry leader satisfying customer expectations with top quality, high performance products and a dedicated service support team. Tuttnauer's sterilization & infection control products are trusted at over 350 000 installations worldwide including Pharmaceutical Production, Research Institutes, Laboratories, Hospitals and Clinics.



### More from Tuttnauer:

Featuring additional Tuttnauer product's for laboratory and life science applications.



Horizontal line of large laboratory sterilizers



Vertical autoclaves for liquid, glassware, and biohazardous waste



Benchtop autoclaves for life science applications



Learn from our Experts

Join our blog [www.tuttnauer.com/blog](http://www.tuttnauer.com/blog)



## Pharma Line

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