Surface Finishing Standards in Steam Sterilizers for cGMP Environments

APPLICATION BRIEF

GETINGE

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Abstract

This brief examines the critical role of surface finish in steam sterilizers used in cGMP pharmaceutical facilities and how material choice and surface roughness affect cleanability, corrosion resistance and microbial control. Key ASME-BPE guidelines (e.g. SD-6.2.4) on surface roughness (Ra) and passivation are highlighted, and Getinge's sterilizer designs and finish options are presented as solutions.

Best practices for specifying finishes (mechanical polish vs. electropolish, and chemical passivation) are summarized, with emphasis on long-term compliance, performance, and ease of validation.

Introduction

In pharmaceutical production, cGMP regulations mandate strict prevention of cross-contamination. All components and equipment contacting the product must be thoroughly cleaned and sterilized on validated cycles. Steam sterilizers form a key part of this workflow. To meet regulatory expectations and maintain product safety, sterilizer interior surfaces must be highly cleanable and corrosion-resistant. Improper finishes can harbor biofilms or contaminants and accelerate corrosion under frequent cleaning. Accordingly, industry standards (ASME BPE) and guidance (ASTM) govern choice of materials and surface treatments. Getinge's cGMP steam sterilizers are engineered to these standards, using high-grade 316L stainless steel and controlled surface finishes to ensure compliance and performance.

Importance of Process Contact Surface Finishes

Material finish is fundamental to hygienic design. Stainless steel (commonly 316L) has no inherent antimicrobial effect, so smooth, defect-free surfaces are relied upon to prevent adhesion and entrapment of microbes. Increased surface roughness correlates strongly with microbial attachment. Studies show significantly more bacterial retention on surfaces rougher of 0.9 µm, compared to 0.8 µm Ra.[1] Thus, hygienic design guidelines set Ra ≤0.8 µm as a practical target to minimize biofilm formation. Smooth surfaces also improve cleanability and reduce wear: tighter Ra means less friction, fewer crevices for debris, and lower corrosion rates. In practice, ASME BPE limits Ra to ≤0.89 µm (35 µin) within the sterile boundary of steam systems, aligning with the evidence above. Correct finish greatly aids sterilization efficacy and reliable operation over the equipment's lifetime.

Selecting the Appropriate Material and Surface Finish

Material: Austenitic stainless steels (particularly 316L) are standard for cGMP sterilizers because of their strength and corrosion resistance. For example, 316L has lower carbon than 304, making it less prone to "rouging" under water or bioburden, an important benefit in clean utilities. In steam sterilizers, 316L is favored for wetted parts (chambers, piping, door plates) to resist caustic cleansers and maintain purity. Other materials (e.g. aluminum or polymers) are generally unsuitable for high-temperature steam and strict GMP use.

Surface Finish: The chosen finish must balance smoothness with practicality. A mechanically polished finish is typically used. For example, higher-grit polishing (e.g. 4000-grit) yields smoother surfaces and better corrosion resistance than coarse polishing. Electropolishing (an electrochemical polishing) can further improve smoothness: it removes a thin layer of metal to eliminate micro-asperities, yielding a highly reflective, "featureless" finish. However, it also requires cost and controlled handling. In steam sterilization applications, ASME BPE does not mandate electropolishing – a fine mechanical polish is often sufficient. In practice, Getinge uses precision-machined and polished 316L for chambers and piping (e.g. Ra <0.51 µm) to meet GMP needs. After fabrication, all stainless surfaces naturally form a protective oxide layer in air (natural passivation), but additional treatment is common (see below).

Key Considerations for Bioprocessing Applications

Surface finish expectations for bioprocessing systems are clearly defined in the ASME BPE 2024. These standards establish the acceptable surface finish parameters necessary for hygienic bioprocessing applications.

Surface Roughness (Ra): Per SD-6.2.4, all surfaces within the sterile boundary must have an Ra that does not exceed 0.89 µm (35 µinch). In practice, Getinge's standard finishes are much finer (typically ≤0.51 µm). Lower Ra improves cleanability and reduces microbial entrapment.

Passivation Requirement: According to ASME BPE E 2.2, all stainless-steel surfaces must undergo passivation after fabrication or welding. Under this standard, Getinge-manufactured bioprocessing sterilizers ensure chemical passivation of all new surfaces during assembly.

Surface Finishing Categories: ASME BPE (Part SD-2.4.4.3 and SF-2.4.1) defines allowable finishing methods (machining, mechanical polishing, electropolishing, etc.) for process-contact parts. Practically, owners specify a finish class (e.g., SF, CF) with target Ra. Getinge's design ensures compliance by using fine mechanical polishing of welded joints and components.

R_a Readings for Metallic Process Contact Surfaces, Mechanically Polished		
	R_a Max.	
Surface Designation	**µin**	**µm**
SF0	No finish requirement	No finish requirement
SF1	20	0.51
SF2	25	0.64
SF3	30	0.76

R_a Readings for Metallic Process Contact Surfaces, Electropolished		
	R_a Max.	
Surface Designation	**µin**	**µm**
SF4	15	0.38
SF5	20	0.51
SF6	25	0.64

In addition to defining surface roughness limits, ASME BPE also categorizes acceptable finishing methods for process-contact surfaces. These are detailed in the SF-2.4.1 and include mechanical polishing, electropolishing, cold working, and machining. The table above summarizes those allowable methods:

Surface Finishing Categories

Electropolishing (EP): Although optional in sterilizer systems, EP can be requested for critical surfaces. ASME BPE notes EP is not required for sterilizers. Nevertheless, EP produces an exceptionally smooth, passive finish. Getinge offers EP as a "special" option; if used, all austenitic stainless parts still receive passivation.

In summary, specifying finishes in GMP steam sterilizers means setting an Ra target (≤35 µin) and applying ASTM A380-style passivation. ASME BPE leaves the method open, but Getinge follows a rigorous process of polish + chemical passivation to meet or exceed the standard in a repeatable way.

The Getinge Solution

Getinge's cGMP Sterilizers for Pharma and Biopharma

Getinge supplies a complete range of steam sterilizers engineered for validated GMP use. These units use high-quality 316L SS and proven control systems to ensure reproducible processes and compliance.

The GSS P Steam Sterilizer is designed for reliable contamination prevention and high productivity. It incorporates a GMP-grade Process Management System (supporting GAMP5 and regulatory requirements), and offers chamber sizes from 0.4 to 9 m³.

The GEV Steam/Air Mixture Sterilizers is ideal for efficient terminal sterilization of packaged liquids.

Getinge cGMP sterilizers utilize 3 different control system options for intuitive operator control across both cleaning and sterilization equipment: Siemens, Allen Bradley or B&R.

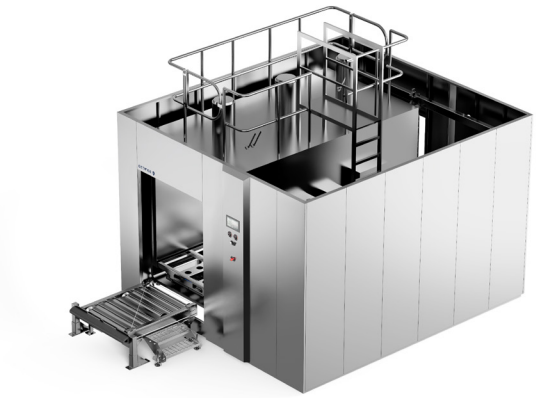
Sterilization Surface Options

Getinge offers multiple finish levels to match user requirements (see decision-tree summary below). By default, all process-contact stainless steel surfaces in Getinge sterilizers are mechanically polished and passivated. The inner chamber and piping come polished to Ra <0.51 µm (≤20 µin), well below the 0.89 µm ASME limit. The inner liner (non critical surface) is polished to less than Ra 0.79 µm. Exterior and secondary surfaces are typically Ra <0.76 µm. All welds and joints are finished smooth and then chemically passivated per ASME-BPE E 2.2.

- **Standard Finish:** Mechanically polished SS with Ra ≤0.51 µm on all sterile-boundary surfaces (chamber, piping, valves). Natural oxidation occurs in air, and components receive thorough cleaning to ensure the passive chromium-oxide layer is intact.
- **Standard Option - Passivation:** Beyond natural passivation in air, Getinge recommends chemical passivation (ASTM A380) for final finish. This controlled nitric-acid treatment removes free iron and enhances the Cr-rich oxide layer without altering tolerances or surface profile. Chemical passivation is fully GMP-compliant, repeatable and traceable, ensuring long-term corrosion resistance in the cleanroom environment.
- **Special Option – Electropolishing:** Available on request for critical parts. Electropolishing produces a microscopically smooth, featureless finish and removes embedded contaminants. If chosen, Getinge applies EP to key areas (e.g. vessel interior, pipes) while still chemically passivating all surfaces afterward. Note ASME BPE does not mandate EP for steam sterilizers, so it is an upgrade for ultra-stringent requirements.

Getinge Biopharma cGMP Sterilizers

GSS P Steam Sterilizer
A high-performance cGMP autoclave designed for component sterilization in biopharma production. It features sanitary stainless-steel construction (robotically welded chamber, satin-finished fascia) for easy cleaning, and offers chambers from 0.4–9 m³ with multiple control options (Siemens, B&R, or Allen-Bradley). The structured HMI set up ensures intuitive operation, minimizing risk of user errors across cycles. This sterilizer's proven design and global support network help pharmaceutical manufacturers maintain uninterrupted, contaminant-free processes.



GEV Steam/Air Mixture Sterilizer
Designed for cGMP compliant terminal sterilization of pharmaceutical products that must be dry and ready for further handling immediately after the cooling phase. It uses a combination of steam and compressed air to balance chamber pressure, allowing pressure-sensitive containers such as vials, glass bottles, and flexible bags to be sterilized without risk of deformation. The GEV provides rapid and versatile terminal sterilization pharmaceutical production environments where process reliability and throughput are critical.

Choosing the Appropriate Surface Finish

How Getinge applies different finish treatments based on part type and application.

ASME-BPE SD-6.2 Steam Sterilizers/Autoclaves	Compliant	Application notes
SD-6.2.4 System Design Surface finish < 0.89 µm	YES	Getinge Standard Mechanically polished Getinge Ra < 0.51 µm for piping and pressure vessel and Ra 0,79 µm for inner liner.
E-2.2 When passivation is necessary: (a) after welding and fabrication (b) after welding of new components into a system	YES	ASME BPE does not specify which method to be used for passivation (This is non-mandatory)
SD-6.2.4 System Design All process contact surfaces within the sterile boundary including tubing, chamber, and components shall be passivated.	YES	Natural passivation of stainless-steel materials in open air or chemical passivation. Chemical passivation with nitric acid is available as a standard option.
SF-2.4.1 Surface Finishing Electropolishing	N/A	Electropolishing non mandatory It is not required for steam sterilization systems.

Recommended Surface Treatments for cGMP Environments

Getinge's preferred approach is mechanical polishing plus chemical passivation because it offers cleanliness and corrosion resistance without altering the surface geometry. This yields a stable, chromium-rich oxide ideal for hygienic use, while minimizing pitting or rouging over time. By contrast, electropolishing is not required for Getinge sterilizers, unless specified for special applications. In all cases, Getinge sterilizer surfaces meet or exceed ASME BPE finish requirements (Ra and passivation) in a repeatable process that facilitates validation and audit compliance.

Conclusion

In cGMP sterilizers, correct surface finishing is a compliance imperative. Smooth, well-passivated stainless-steel surfaces enable thorough sterilization, reduce biofilm risk, and extend equipment life. By adhering to ASME BPE finish limits (Ra ≤0.89 µm) and ASTM passivation practices, facility operators ensure both regulatory compliance and operational excellence. Getinge's sterilizers are engineered with these standards in mind – precision-polished 316L interiors, robust HMI controls, and defined finish options give users confidence in long-term performance. Ultimately, investing in the right material grades and finish protocols pays off through reliable sterilization cycles, easier cleaning/qualification, and lower lifecycle costs for pharmaceutical production.

References

1. Arnold J. W., Bailey G. W. (2000). Surface finishes on stainless steel reduce bacterial attachment and early biofilm formation: scanning electron and atomic force microscopy study. Poult. Sci. 79: 1839–1845

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With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

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