

Mucosal-Contact Photopolymer Devices: Saliva, Mechanical Cycling, Biofilm, Extractables and Use-State Qualification

An integrated framework for oral and other mucosal devices in repeated service

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Abstract

Mucosal-contact photopolymer devices operate in a coupled chemical, mechanical and microbial environment. Saliva or other secretions wet and transport constituents; temperature and pH change over time; mastication, speech, insertion and removal impose cyclic load; finishing controls roughness and plaque retention; cleaning changes both chemistry and surface; and biofilm can alter local exposure and mechanical reliability. Qualification cannot be reduced to immersion in water, a dry flexural test or one cytotoxicity result. This review defines a use-state framework for oral and other mucosal-contact devices made by vat photopolymerisation. It freezes the final device-process configuration, maps direct and indirect contact, builds a secretion and thermal-cycle model, quantifies time-resolved release, couples fatigue and wear to surface and fit, and treats biofilm as an exposure modifier rather than a single microbial count. Evidence is integrated through non-compensatory gates for chemistry, mucosal response, mechanics, biofilm, hygiene and lifecycle stability. Published dental studies illustrate process-sensitive monomer release, saliva-ageing effects, microbial adhesion and biofilm-dependent strength variability, but their material-specific results are not generalised. The output is a traceable qualification plan without proprietary formulation or universal acceptance limits. Keywords: mucosal contact; photopolymer; saliva; mechanical cycling; biofilm; extractables; dental device; use-state qualification

1. Significance, scope and ownership

ISO 10993-1:2025 requires biological evaluation to reflect the finished device, nature and duration of contact and intended use [1]. Mucosal devices often combine continuous wet contact, intermittent peak load, repeated insertion, cleaning and a living microbial environment. Their qualification therefore depends on the complete use state.

1.1 Corpus boundary

ER-256 owns mucosal-contact qualification across saliva or analogous secretions, mechanical cycling, biofilm, extractables and service-state integration. ER-175 retains washing-system engineering; ER-181 retains post-cure engineering; ER-206 retains micro-computed-tomography metrology. ER-251 owns biological-evaluation planning; ER-252 owns cytotoxicity-test artefacts; ER-253 owns analytical thresholds and coverage; ER-254 owns constituent toxicological risk; ER-255 owns skin-contact wearables; ER-257 to ER-259 own blood, bone-interface and antimicrobial-specific questions; and ER-260 owns patient-specific digital traceability. ER-256 does not convert an application-specific result into a universal material claim.

2. Freeze the final device state

Record resin designation, printer, wavelength, orientation, layer schedule, wash, drying, post-cure, support removal, polishing or glazing, coating, bonding, assembly, disinfection or sterilisation, packaging and age. Include internal surfaces, occlusal or load-bearing regions and interfaces that are difficult to finish. The test article should represent the worst credible clinically used surface and geometry. A flat polished disk cannot alone qualify channels, intaglio surfaces, support scars or thin flexural regions.

3. Map mucosal and fluid-path contact

Define anatomical site, direct or indirect contact, exposed area, continuous and cumulative duration, secretion flow, swallowing or clearance, device motion and neighbouring tissues. Separate local-contact dose from systemically ingested or absorbed dose. Include vulnerable mucosa, reduced salivary flow, inflammation, wounds, paediatric use and repeated multi-device exposure where relevant. The claim should state the evaluated population and exclusions.

4. Build a representative saliva or secretion model

Specify composition, pH, ionic strength, proteins or mucins where relevant, flow or replenishment, temperature and microbial state. Artificial saliva is a model, not a universal surrogate for every person or mucosal site. Use static, refreshed or flowing conditions according to the question. Replenishment can maintain a concentration gradient and increase cumulative release; static extraction can instead overstate local accumulation.

5. Represent thermal and pH cycling

Define clinically plausible temperature extremes, dwell times, transition rates, sequence and total cycles. Include acidic or alkaline challenges only when foreseeable. Verify that acceleration does not create a degradation pathway absent from use.

Measure dimensional change, mass, hardness, modulus, strength, colour, roughness and chemical release at justified intervals. A final endpoint alone can miss an early release burst or transient loss of fit.

6. Quantify time-resolved release

A simplified interval concentration can be represented as $C_{\text{release}} = Q_{\text{interval}} N_{\text{device}} / V_{\text{fluid}}$ where C_{release} is the modelled constituent concentration for the interval, Q_{interval} is the measured or conservatively available mass released per device in that interval, N_{device} is the maximum simultaneous device-equivalents and V_{fluid} is the effective refreshed or retained fluid volume. Flow, swallowing, adsorption and tissue transfer require separate justified terms.

7. Design extraction and sample preparation

ISO 10993-12:2021, together with Amendment 1:2025, addresses sample preparation and reference materials [2,8]. The public ISO record confirms that the amendment applies to the 2021 standard; no additional amendment-specific technical claim is inferred here. Preserve surface-area or mass ratios, extraction vehicle, temperature, duration, agitation, container, headspace, pooling and storage. Use final devices or justified worst-case representatives.

Do not use aggressive extraction as a direct estimate of clinical exposure without translation. Pair exaggerated extractables with simulated-use leachables when the distinction affects risk.

8. Characterise constituents and degradants

ISO 10993-18:2020, together with Amendment 1:2022 on determination of the uncertainty factor, defines the chemical-characterisation framework for device materials, manufacturing-introduced substances, extractables, leachables and relevant degradation products [3,9]. Apply orthogonal analytical coverage and retain unknowns and uncertainty. Link each result to the process and ageing state. Saliva, enzymes, cleaning agents, temperature and biofilm can generate or mobilise species that are absent in a fresh-water extract.

9. Control post-processing effects

Turkalj, Pully, Li, Sun, Ghosh, Čokić, Vanoirbeek, Van Meerbeek and Van Landuyt measured degree of conversion, monomer elution and cytotoxicity in three printed dental composites and found material- and post-processing-dependent behaviour [4]. Their numerical results apply only to the tested materials and protocols. Qualification should record wash solvent history, bath loading, cure spectrum, irradiance, temperature, orientation and time after manufacture. Process changes require biological and chemical impact assessment.

10. Evaluate mucosal biological response

Select evidence according to the hazard map: cytotoxicity, irritation, sensitisation, local inflammation, genotoxicity or other relevant endpoints. Match extraction and dose to mucosal contact and interpret endpoint-specific limitations. A favourable cell-viability result does not close oxidative stress, irritation, sensitisation or long-term degradation. Conversely, an exaggerated extract response requires exposure translation before a clinical conclusion.

11. Characterise surface and finish

Measure areal roughness, waviness, pores, support scars, polishing direction, glaze continuity, contact angle and surface free energy at clinically relevant scales. Repeat after saliva, cleaning and mechanical cycling. Kim, Çakmak, Jo, Jee, Cho, Yoon and Yilmaz found that material type and finishing affected roughness, wettability, protein adsorption and microbial adhesion after artificial-saliva ageing [5]. Those fixed-prosthesis materials illustrate coupled surface-biofilm behaviour, not a universal preferred finish.

12. Model mechanical cycling

Represent mastication, speech, insertion, removal, clenching, flexure and contact with opposing structures as applicable. Control load, waveform, frequency, contact geometry, lubrication, temperature and cycle count. Combine with wet ageing when the material is environment-sensitive. A cumulative screening index can be written as $D_{cycle} = \sum(n_i / N_i)$ where D_{cycle} is a linear cycle-usage index, n_i is the applied number of cycles at load state i , and N_i is the experimentally determined cycles to the defined failure criterion at that state. The model is only a planning approximation and requires validation for nonlinear, sequence-dependent photopolymer damage.

13. Measure wear, debris and fit together

Quantify volumetric or profile wear, antagonist effects, debris, roughness evolution and dimensional fit. Wear can both alter mechanics and expose a chemically different subsurface. Retain and characterise debris when it contributes to mucosal or systemic exposure. Do not infer clinical fit from bulk strength. Thin regions, internal stresses, anisotropy and water plasticisation can drive local deformation before catastrophic failure.

14. Treat biofilm as a system variable

Specify organisms, inoculum, growth medium, saliva conditioning film, flow, oxygen, temperature, duration and cleaning interruptions. Report biomass or counts together with spatial distribution, viability, community composition and surface state. Uehara, de Lima, Sardi, de Figueiredo, Shibli, Asbi, Haim and Rodrigues compared a 39-species subgingival biofilm on three printable resin-based composites and an acrylic control, showing material-dependent biofilm quantity and composition [6]. The in vitro model does not predict clinical disease by itself.

15. Link biofilm to mechanical reliability

Biofilm acids, enzymes and retained moisture can modify the surface and local stress environment. May, Ng, Rosa and Foong exposed appliance resins to pooled saliva, water or a *Streptococcus mutans* biofilm and found that biofilm reduced strength reliability even when characteristic strength was relatively preserved [7]. Qualification should therefore examine distributions and failure probability, not only mean strength. Biofilm effects remain material-, geometry- and protocol-specific.

16. Validate hygiene and cleaning

Define user-cleaning agents, concentration, time, temperature, brushing, rinsing and drying. Evaluate soil and biofilm removal together with residues, surface damage, chemical release, colour and fit across the claimed number of cycles. An antimicrobial claim requires its own durability evidence under ER-259. ER-256 evaluates whether the hygiene procedure controls use-state contamination without degrading the device or increasing exposure.

17. Address use-state interactions

Mechanical cycling can roughen the surface and increase retention; biofilm can change chemistry and reliability; cleaning can remove biofilm yet damage a coating; saliva can plasticise the network and change fit. Use a causal matrix to select combined challenges. Avoid uncontrolled maximal combinations that produce uninterpretable failure. Each combined test should isolate a credible mechanism and preserve a suitable control.

18. Use non-compensatory gates

Gate	Required evidence	Blocking failure
Device state	Final process, geometry, finish and age	Evidence is not representative
Contact model	Site, duration, area, population and fluid path	Exposure cannot be bounded
Fluid model	Composition, flow, pH and temperature cycling	Immersion result is not transferable
Chemistry	Time-resolved release, coverage and uncertainty	Toxicological input is incomplete
Biology	Endpoint-valid mucosal evidence	Tissue response remains unresolved
Mechanics	Wet cycling, wear, debris and fit	Service claim is unsupported
Biofilm	Relevant community, conditioning and surface state	Microbial interaction is unbounded
Hygiene	Cleaning efficacy, residues and lifecycle damage	Reuse claim is unsupported

No favourable gate compensates for another gate's failure. Resolution can require targeted chemistry, process correction, redesign, additional biological evidence, revised cleaning or a narrower claim.

19. Define service-life endpoints

Predefine failure criteria for fracture, permanent deformation, fit loss, unacceptable roughness, coating failure, release increase, discolouration, persistent odour, biofilm retention and cleaning damage. Link each criterion to an inspection or replacement rule. Service life should be bounded by the earliest critical endpoint, not by the most durable property. Preserve failure distributions and uncertainty.

20. Control changes and transfers

Reassess formulation, supplier, pigment, printer, optical source, layer schedule, wash, cure, orientation, geometry, finish, coating, sterilisation, packaging, saliva model, cycling protocol, cleaning instructions and intended duration. Manufacturing-site or laboratory transfer requires comparability evidence.

21. Minimum reporting set

Report intended use, anatomical site, population and duration; full material-process-device state; secretion and thermal model; extraction and time-resolved release; analytical coverage; toxicological routing; mucosal endpoints; surface and finish; wet mechanical cycling; wear, debris and fit; biofilm design; cleaning validation; combined challenges; uncertainty; service-life criteria and change triggers.

22. Knowledge boundary

The standards define current biological, sample-preparation and chemical-characterisation principles [1-3]. Primary studies demonstrate process-sensitive monomer release, finish-dependent adhesion, material-dependent multispecies biofilm and biofilm-associated changes in reliability [4-7]. None establishes a universal safe oral resin, process, cleaning protocol or service life.

23. Limitations

References [1-3] were verified from official ISO records; references [4-7] were examined at full-text or detailed primary-record depth. Dental studies dominate the available application evidence and should not be transferred automatically to other mucosal sites. This review does not disclose proprietary formulations or prescribe product-specific acceptance limits.

24. Conclusions

Mucosal-contact qualification must reproduce the finished device in a wet, cyclic, microbially active and repeatedly cleaned use state. Chemistry, mucosal response, mechanical durability, surface evolution, biofilm and hygiene are separate gates with causal interactions. A defensible claim is bounded to the tested geometry, process, population and service interval and carries explicit replacement and change-control rules.

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