

Skin-Contact Wearables Made from Photopolymers: Occlusion, Sweat, Friction, Sensitisation and Long-Term Use

A use-state qualification framework for prolonged and repeated epidermal contact

Juan Segurola

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Correspondence: info@3Dresyns.com · www.3Dresyns.com

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Abstract

A skin-contact wearable made by vat photopolymerisation is a device-skin system, not merely a cured material. Occlusion changes hydration and barrier function; sweat changes ionic strength, pH and transport; motion produces friction, pressure and microclimate cycling; cleaning and ageing modify the surface; and residual or newly generated constituents can create irritation or sensitisation hazards. A one-time material assay under dry, static conditions therefore cannot qualify prolonged or repeated wear. This review defines a risk-based architecture for qualifying photopolymer wearables in their finished, clinically relevant use state. It freezes the print, wash, cure, finish, cleaning and ageing configuration; maps anatomical contact, duty cycle and vulnerable populations; separates irritation from sensitisation; combines chemical characterisation with occluded extraction and simulated-sweat exposure; and evaluates pressure, shear, roughness, moisture accumulation and mechanical durability as interacting but non-interchangeable evidence. Non-compensatory gates prevent favourable cytotoxicity, chemistry or mechanics from masking an unresolved dermal hazard. The result is a traceable qualification plan with predefined escalation, wear-stop and change-control rules, without prescribing a universal process window or product-specific acceptance limit. Keywords: skin-contact wearable; photopolymer; occlusion; sweat; friction; irritation; sensitisation; long-term use

1. Significance, scope and ownership

ISO 10993-1:2025 places biological evaluation within risk management and requires evidence relevant to the nature and duration of body contact [1]. For wearables, the real exposure is shaped by geometry, fit, occlusion, motion, sweat, hygiene and repeated use. Qualification must therefore represent the final device and its use state.

1.1 Corpus boundary

ER-255 owns skin-contact wearable qualification across occlusion, sweat, friction, irritation, sensitisation and long-term wear. ER-175 retains washing-system engineering; ER-181 retains post-cure engineering; ER-206 retains micro-computed-tomography metrology. ER-251 owns device-level biological-evaluation planning; ER-252 owns cytotoxicity-test artefacts; ER-253 owns analytical thresholds and chemical coverage; ER-254 owns constituent toxicological risk assessment; ER-256 owns mucosal-contact qualification; ER-257 to ER-259 own blood, bone-interface and antimicrobial-specific questions; and ER-260 owns patient-specific digital traceability. ER-255 integrates their outputs only as inputs to the skin-contact decision.

2. Freeze the finished wearable

Record resin designation, printer, wavelength, layer schedule, build orientation, wash chemistry and history, drying, post-cure spectrum and dose, support removal, finishing, coating, adhesive, textile or electrode interface, sterilisation or disinfection, packaging and shelf age. Define production variability and worst credible residual state. The skin-facing surface should not be replaced by a polished laboratory coupon unless polishing is the qualified production state. Channels, recesses, seams and adhesive boundaries can retain liquid or concentrate stress and require representation.

3. Define contact anatomy and duty cycle

Map each contact region, load-bearing edge, occluded area and intermittent interface. Record continuous wear time, cumulative daily wear, removal intervals, service life, reuse, cleaning frequency, environmental temperature, activity level and sleep use. Include foreseeable tight fitting, swelling, strap adjustment and migration. A nominal contact duration is insufficient when high local pressure or sweat accumulation creates a more severe exposure.

4. Identify susceptible populations

Consider children, older adults, atopic or damaged skin, diabetes, vascular impairment, reduced sensation, excessive sweating, occupational heat exposure and known acrylate allergy. Body mass alone does not capture local dermal vulnerability. Qualification claims should state the evaluated population and exclusions. Risk controls can include wear-time limits, fit checks, barrier layers, replacement intervals and clinical supervision.

5. Treat occlusion as an exposure multiplier

Occlusion reduces evaporation, raises hydration and temperature and can increase penetration, maceration and susceptibility to mechanical damage. Measure the microclimate at representative sites and duty cycles rather than assuming ambient conditions. Compare open, partially occluded and worst credible occluded configurations. The backing, liner and edge seal are part of the exposure system even when they are not photopolymers.

6. Simulate sweat without oversimplifying it

Select a justified artificial-sweat composition, pH, ionic strength, temperature, flow or replenishment and exposure time. Where the use population or activity can change composition, challenge appropriate boundaries. Include drying and rewetting when these occur in use. Sweat simulation supports transport, surface and mechanical questions; it is not itself a biological safety test. Analyse both released constituents and changes in mass, dimensions, hardness, roughness, colour and surface chemistry.

7. Express local chemical challenge

A screening estimate of cumulative local loading can be represented as $C_{\text{skin}} = \sum(m_i f_i) / A_{\text{contact}}$ where C_{skin} is cumulative transferred mass per contact area, m_i is the available or measured mass of constituent i over the declared interval, f_i is its justified transfer fraction to skin, and A_{contact} is the effective contact area. The value must retain time, occlusion and uncertainty; it is not a universal irritation or sensitisation threshold.

8. Distinguish irritation from sensitisation

Irritation is a local inflammatory response driven by exposure intensity and tissue condition. Sensitisation is immune induction followed by possible elicitation at later exposure. A device can pass one endpoint and fail the other. ISO 10993-10:2021 addresses skin-sensitisation assessment [2]. ISO

10993-23:2021, together with Amendment 1:2025, addresses irritation and includes pre-test, in vitro and in vivo considerations [3,8]. The amendment adds additional in vitro reconstructed human epidermis models; applicable controlled texts govern method selection.

9. Do not infer finished-part safety from liquid-resin labels

Bowers, Ranpara, Roach, Knepp, Arnold, Stefaniak and Virji chemically analysed 39 light-curing additive-manufacturing products and found irritants and sensitisers not fully represented by safety-data-sheet ingredient lists [4]. That study concerned feedstocks and occupational assessment, but it demonstrates why formulation disclosure alone cannot close dermal risk. Conversely, a hazardous liquid ingredient does not prove that a qualified finished part releases a relevant dose. Finished-device chemistry, processing and use-state exposure are required.

10. Make post-processing a controlled biological variable

Brooks and Yadavalli experimentally showed that wash and post-cure protocols changed cytotoxicity for three printed photopolymers [5]. Their conditions do not define a universal safe process, but they establish that process history can alter biological evidence. Record elapsed time between washing, curing, finishing and testing. Requalify after changes in solvent, bath loading, agitation, cure spectrum, irradiance, temperature, orientation or part thickness.

11. Evaluate sensitisation with chemical context

Raison-Peyron, Caillol, Bourrain, Ibeka and Negrell combined patch testing and proton NMR in three allergic-contact-dermatitis cases involving hobby UV resins and identified methacrylate sensitisation with specific resin constituents [6]. These uncured consumer exposures differ from qualified wearables, so the study establishes plausibility, not product risk. For finished devices, link detected or plausible leachables to sensitisation evidence and identity confidence. Unknown peaks, structural alerts and patient history should drive targeted analysis or clinical restrictions rather than being assigned zero risk.

12. Characterise the skin-facing surface

Measure relevant areal roughness, waviness, edge radius, support scars, porosity, coating continuity and contamination. Inspect after cleaning and ageing, not only after manufacture. Surface metrics should resolve the spatial scale that interacts with skin. Replicate skin-facing orientation and finishing. A mean roughness value can hide isolated sharp asperities or seams that dominate local injury.

13. Quantify friction and shear

For a simplified sliding interval, frictional work can be represented as $W_{fr} = \mu N s$ where W_{fr} is frictional work, μ is the condition-specific coefficient of friction, N is normal load and s is sliding distance. Real wear requires time-varying load, motion path, sweat state and contact area; the expression is a bookkeeping model, not a tissue-damage law. Kasar, Chan, Shamanaev and Menezes measured tribological interaction of printed polymers against a water-responsive skin model and found material and hydration-dependent behaviour [7]. Their polyurethane and polyamide results support use-state tribology but cannot rank photopolymer wearables.

14. Map pressure and fit

Measure pressure distribution under representative anatomy, posture, swelling and strap adjustment. Report high-percentile local values and dwell time in addition to averages. Edge and prominence loading may dominate discomfort or injury.

Use anatomically relevant surrogates or human-factors studies when justified. A rigid flat platen cannot reproduce curvature, soft-tissue compliance or motion-induced redistribution.

15. Combine chemical and mechanical exposure

Friction can disrupt barrier function and increase access of leachables; occlusion can increase hydration and friction; sweat can change both transport and surface mechanics. Test combinations selected from a causal hazard map instead of multiplying every factor indiscriminately. A favourable dry-friction result does not compensate for adverse wet chemistry, and a clean extractables profile does not compensate for damaging pressure or shear.

16. Age the complete use state

Cycle sweat, drying, temperature, ultraviolet exposure where relevant, cleaning agents, disinfection, flexure, abrasion and donning/doffing. Examine cumulative changes in release, surface, fit and strength. Justify acceleration and verify that it does not introduce an unrealistic degradation mechanism. Test both new and end-of-life states. If a coating or liner is a risk control, demonstrate its integrity and define inspection and replacement criteria.

17. Use non-compensatory gates

Gate	Required evidence	Blocking failure
Device state	Final process, finish, accessories and ageing	Test article is not representative
Contact	Anatomy, area, pressure and duty cycle	Exposure cannot be bounded
Microclimate	Occlusion, temperature and moisture evidence	Dry testing is not transferable
Chemistry	Sweat-relevant release and uncertainty	Dermal dose remains unresolved
Irritation	Endpoint-valid evidence under relevant exposure	Local inflammatory risk remains open
Sensitisation	Constituent and device evidence with alerts addressed	Immune hazard remains open
Mechanics	Wet friction, pressure, roughness and durability	Tissue-damage pathway remains open
Lifecycle	Cleaning, ageing and replacement controls	Long-term claim is unsupported

Passing one gate cannot average away failure of another. Escalation can require process correction, targeted chemistry, endpoint testing, design change, reduced duty cycle or an explicit residual-risk decision.

18. Predefine wear-stop and escalation rules

Define responses to persistent erythema, pain, blistering, maceration, ulceration, unexpected odour, surface tack, cracking, delamination, fit change and repeated user complaint. State who evaluates the event and whether the device is cleaned, replaced, quarantined or investigated. Clinical monitoring does not replace premarket qualification, but it closes the lifecycle feedback loop and can reveal population or use conditions absent from laboratory models.

19. Control cleaning and reuse

Validate cleaning efficacy and residues together. A stronger cleaning agent can reduce soil yet extract, swell or embrittle the photopolymer. Track cumulative cycles, drying and user execution. If reuse is claimed, define maximum cycles and inspection criteria. Transfer from professional to home cleaning requires a new usability and exposure assessment.

20. Minimum reporting set

Report intended use, population, contact anatomy and duration; device and accessory materials; complete process state; fit and pressure map; occlusion and microclimate; sweat model; chemical release; irritation and sensitisation rationale; friction and roughness; combined-exposure design; ageing and cleaning; test-article selection; deviations; uncertainty; wear-stop rules; residual risk and change triggers.

21. Knowledge boundary

The standards define current biological, sensitisation and irritation frameworks [1-3]. Primary studies show incomplete feedstock disclosure, process-sensitive cytotoxicity, methacrylate sensitisation plausibility and hydration-dependent tribology [4-7]. They do not establish a universal safe resin, wash/cure schedule, wear duration or friction limit.

22. Limitations

References [1-3] were verified from official ISO records; references [4-7] were examined at full-text or detailed primary-record depth. This review does not provide legal advice, replace clinical judgement, disclose proprietary formulations or prescribe product-specific acceptance limits.

23. Conclusions

Skin-contact qualification must represent the finished wearable under occlusion, sweat, pressure, motion, cleaning and ageing. Irritation, sensitisation, chemical release and mechanical injury are distinct gates linked by the use state. A defensible claim identifies the evaluated population and duty cycle, preserves uncertainty and carries explicit wear-stop, replacement and change-control rules.

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