ISO 10993

Biological evaluation of medical devices (multi-part series)

Condensed Practical Reference & Field Checklists

Prepared for teams involved in refurbishing, sourcing replacement parts for, or re-exporting medical devices that include patient-contacting components (cuffs, sensors, tubing, electrodes, masks).

Important note on scope and use: *This document is an original, independently written condensed overview and practical checklist tool. It summarizes, in the author's own words, the general risk-based framework of the ISO 10993 series (biological evaluation of medical devices) for quick field reference. It is* ***not a reproduction of the official standard text****, is not a substitute for it, and must not be used as the sole basis for a biological safety determination, certification, or regulatory submission. Biological evaluation, and any decision to rely on equivalence rather than new testing, should be made or reviewed by a qualified toxicologist or biocompatibility specialist against the current officially licensed ISO 10993 series text.*

1. About This Standard Series

ISO 10993 is a multi-part series addressing the biological safety of materials and devices that contact the human body — evaluating whether a material could cause harmful biological reactions such as irritation, toxicity, or allergic sensitization. Rather than mandating a fixed set of tests for every device, it defines a **risk-based framework** (led by Part 1) that determines which specific biological endpoints need to be evaluated, based on how and how long the device contacts the body.

1.1 Why it matters for refurbishment specifically

- Refurbishment frequently involves replacing patient-contacting components — blood pressure cuffs, SpO2 sensors/probes, ECG electrodes/leads, breathing circuit masks, tubing — parts explicitly within scope of biological evaluation.
- Using a component from a **different material or a different original manufacturer** than the device was originally validated with means the original biocompatibility data may no longer directly apply — this is a commonly overlooked gap in refurbishment quality processes.
- A documented **equivalence argument** (same material, same manufacturing process, same or lesser contact duration/type as an already-evaluated part) can sometimes avoid the need for new biological testing — but this argument needs to be made and recorded deliberately, not assumed informally.
- This connects directly to the ISO 14971 risk file (see the companion guide) — biological risk from patient-contact materials is one of the hazard categories a thorough risk analysis should explicitly cover.

2. The Risk-Based Framework (Part 1 Concepts)

ISO 10993-1 categorizes body contact by two dimensions, then uses that categorization to determine which biological endpoints are relevant to evaluate.

Contact category	General description
Surface device	Contacts intact skin (e.g. electrodes, external sensors), mucosal membranes (e.g. masks, some probes), or a compromised/breached surface.
External communicating device	Contacts the circulating blood path indirectly, contacts tissue/bone/dentin, or contacts circulating blood directly (e.g. some catheters, blood-contacting tubing sets).
Implant device	Contacts tissue/bone or blood on a longer-term or permanent basis inside the body — not typical for the refurbished ward/monitoring equipment category, but relevant for certain device types.

Duration category	General description
Limited exposure	Single use or multiple use up to 24 hours total contact.
Prolonged exposure	Contact beyond 24 hours and up to 30 days total.
Permanent exposure	Contact beyond 30 days total.

The combination of contact type and duration determines which biological endpoints (from the list below) are typically relevant to evaluate for a given component.

3. Common Biological Endpoints Considered

Endpoint	What it assesses
Cytotoxicity	Whether the material damages or kills cells in contact with it — a baseline test for almost all patient-contacting materials regardless of contact duration.
Sensitization	Whether the material could provoke an allergic reaction on repeated or prolonged contact.
Irritation	Whether the material causes local tissue irritation at the site of contact.
Systemic toxicity (acute/sub-acute/sub-chronic/chronic)	Whether substances that could leach from the material cause broader toxic effects, relevant especially for longer contact durations.
Material-mediated pyrogenicity	Whether the material could cause a fever response.
Genotoxicity	Whether the material could cause damage to genetic material — typically relevant for longer-duration or implant contact.
Hemocompatibility	Relevant for any component contacting blood — assessing effects on clotting, hemolysis, and blood cell/protein interactions.
Chemical characterization	Identifying and quantifying extractable/leachable substances from the material, increasingly used as a foundation for a toxicological risk assessment rather than jumping straight to animal or cell-based testing.

4. Practical Path: Equivalence vs. New Testing

When a patient-contacting component is replaced during refurbishment, there are generally two practical paths, and the choice should be documented as a deliberate decision, not a default assumption:

- **Equivalence argument:** if the replacement part is made from the same material, by the same manufacturing process, with the same or a less demanding contact type/duration as a part already biologically evaluated (e.g. the original OEM part, or a part already used and evaluated elsewhere in your product line), a documented equivalence rationale may be sufficient — citing the specific prior evaluation being relied upon.
- **New evaluation:** if the replacement material, manufacturing process, sterilization method, or contact profile differs meaningfully from anything previously evaluated, new biological testing (or at minimum a chemical characterization plus toxicological risk assessment) should be considered, ideally with input from a qualified biocompatibility specialist.
- **When in doubt, treat it as new** — an incorrect equivalence claim is a more serious quality and safety gap than the cost of conservative additional evaluation.

5. Practical Field Checklists

Use these as a starting self-assessment tool. They do not replace a formal biological evaluation report prepared or reviewed by a qualified specialist.

A. Patient-Contact Component Change Checklist

Check Item / Action	Status
■ All patient-contacting components in the device identified (cuffs, sensors, electrodes, tubing, masks, probes).	Y / N / NA
■ For each component being replaced during refurbishment, contact type (surface/external-communicating/implant) and duration (limited/prolonged/permanent) confirmed.	Y / N / NA
■ Replacement part's material and manufacturing process compared against the original/previously evaluated part.	Y / N / NA
■ Equivalence argument documented where claimed, citing the specific prior evaluation relied upon.	Y / N / NA
■ New evaluation triggered and scoped where equivalence cannot be reasonably claimed.	Y / N / NA
■ Sterilization method (if applicable) for the replacement part reviewed for any biological compatibility impact.	Y / N / NA

B. Documentation & Risk File Checklist

Check Item / Action	Status
■ Biological evaluation conclusion (equivalence or new testing outcome) filed with the device's technical documentation.	Y / N / NA
■ Biological risk explicitly reflected as a hazard category in the device's ISO 14971 risk management file.	Y / N / NA
■ Supplier documentation for replacement patient-contact parts retained (material specification, manufacturer's own biocompatibility data where available).	Y / N / NA
■ Any change in patient-contact material disclosed transparently in technical documentation provided to the buyer/regulator.	Y / N / NA
■ Complaint/field-feedback channel able to capture and flag any reported skin/tissue reaction for follow-up and reassessment.	Y / N / NA

Reminder: *biological evaluation decisions, especially equivalence claims, should be made or reviewed by a qualified toxicologist or biocompatibility specialist against the current ISO 10993 series text and applicable regional guidance (e.g. FDA or EU MDR expectations for biological evaluation).*