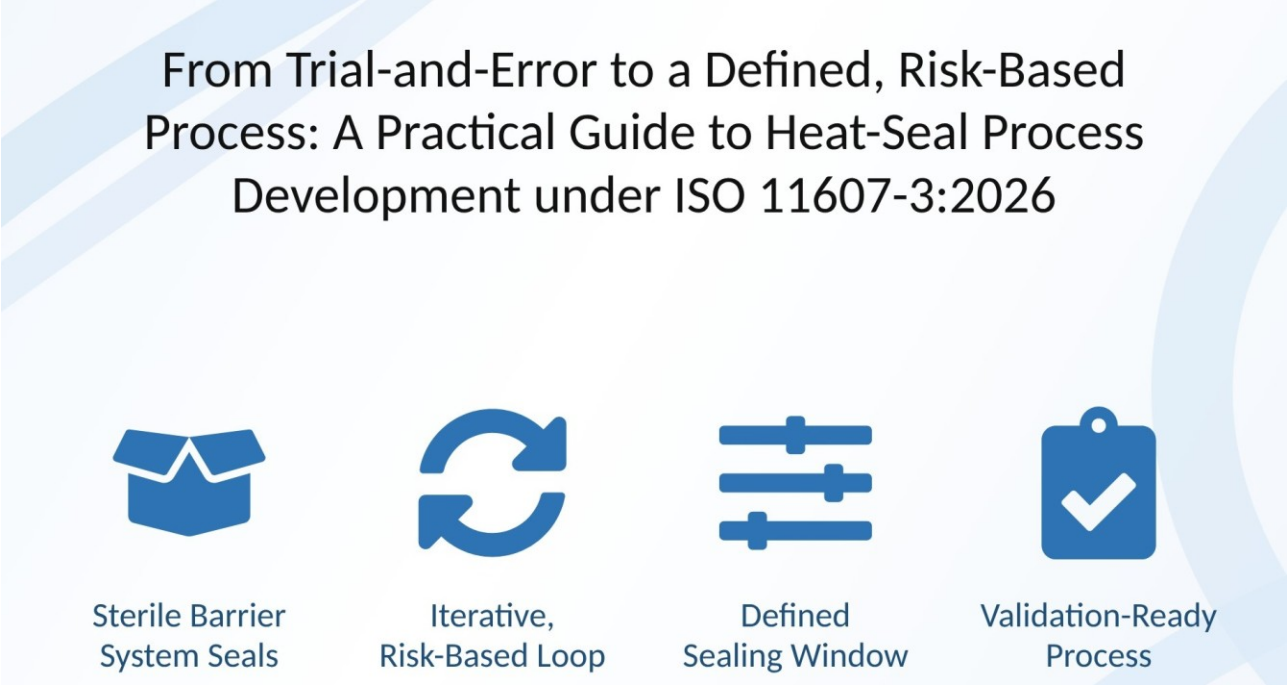


ISO has published ISO 11607-3:2026 (first edition, September 2026), 'Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly'. It fills a long-standing gap in the ISO 11607 series: Part 1 covers the design of sterile barrier systems (SBS) and Part 2 covers the validation of forming, sealing and assembly processes, but neither explained how to develop a heat-sealing process before trying to validate it.

This white paper explains, clause by clause and in plain language, what ISO 11607-3 requires, why each requirement matters on the production floor, and what manufacturers need to do in real life to comply. Each requirement is translated into concrete actions, supported by diagrams, a compliance action plan, auditor Q&A and a clause-by-clause compliance checklist (Appendix).

The key message is simple: ISO 11607-3 does not add a new validation stage. It formalizes the work that should happen before IQ, OQ and PQ — start from the SBS specification, analyse the process risks, find the sealing window with data, define controls, and loop until the risk is acceptable. It also provides a documented equivalence route for new, moved or refurbished sealers. Heat-sealing processes already validated to ISO 11607-2 are regarded as sufficiently developed and need no additional work (5.1.1).

1. Background: Where ISO 11607-3 Fits

1.1 What the New Standard Is

ISO 11607-3 was prepared by ISO/TC 198, Sterilization of health care products, in collaboration with CEN/TC 102 under the Vienna Agreement. It applies to industrial manufacturers of preformed sterile barrier systems (pouches, bags, reels) and to medical device manufacturers that form and seal their own SBS, and it is intended to be used prior to process validation.

Attribute	What the standard says	What it means in practice
Title	Part 3: Requirements for process development for forming, sealing and assembly	A 'how to develop' standard that sits between design (Part 1) and validation (Part 2)
Edition	First edition, 2026-09	New document; no previous version to transition from
Technology covered	Heat sealing that creates a microbial barrier (thermal fusion)	Bar, impulse, rotary/band, blister tray, form-fill-seal and platen sealers
Not covered	Cold sealing; containment-only seals; wrap spot welds; thermoforming	These processes stay under ISO 11607-1/-2 only
When used	Prior to process validation	The output is a process specification that feeds IQ, OQ and PQ
Normative references	ISO 11607-2:2019 and ISO 11607-2:2019/Amd 1:2023	Risk management must follow Amendment 1 (Annex B of Part 2)
Existing processes	Validated processes are sufficient evidence of development (5.1.1)	No retrospective development work is needed for validated lines
Competence expected	Proficiency in design of experiments (DOE) and access to test resources	Teams need DOE skills and validated seal strength / integrity test methods
Informative annexes	A: process parameters; B: sealing materials; C: equipment features; D: FMEA example; E: equivalence statistics	Practical guidance that auditors will expect you to have considered

1.2 Why the Standard Matters

The heat seal is often the weakest link of a sterile barrier system. Until now, many teams moved straight from a package design to validation runs and discovered problems late: seals that failed at the edge of the range, settings that did not transfer between machines, or failures caused by factors nobody had analysed. ISO 11607-3 closes that gap by requiring a structured, risk-based development process whose output is a robust, validation-ready process specification. Figure 1 shows where Part 3 fits in the ISO 11607 family.

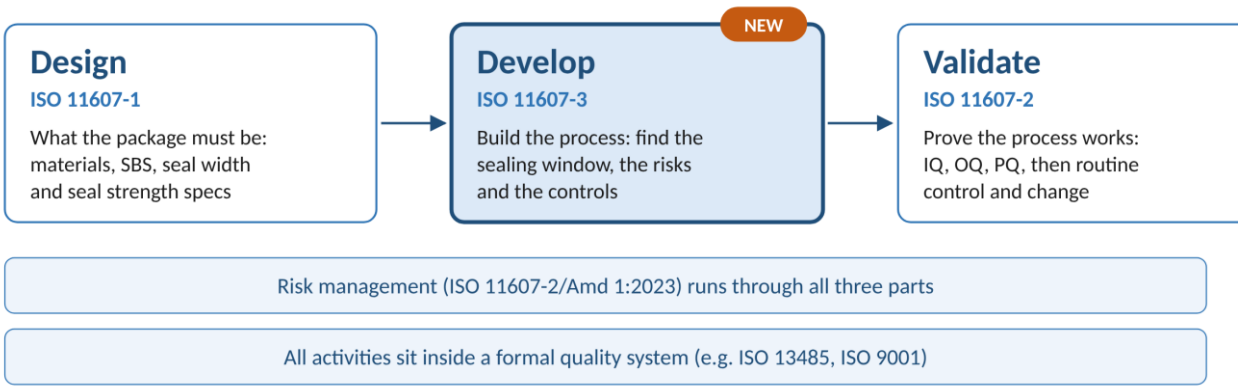


Figure 1 — Where ISO 11607-3 fits: design (Part 1), develop (Part 3), validate (Part 2)

2. High-Level Summary of Requirements

The table below maps each requirement area at a glance. Each item is explained, with practical compliance guidance, in Section 3.

#	Area	What It Requires	ISO 11607-3 Clause(s)
1	Quality system	All development activities carried out within a formal quality system (e.g. ISO 13485, ISO 9001)	§4.1
2	Risk management	A risk management process conforming with ISO 11607-2/Amd 1:2023	§4.2
3	Sampling	Statistically valid sampling for validation; a statistical rationale is recommended during development	§4.3
4	Test methods	Test methods validated per ISO 11607-2; preliminary (unvalidated) evaluation methods allowed during development	§4.4
5	Documentation	Records meeting ISO 11607-2:2019, 4.5	§4.5
6	Scope of development	Applies to processes not yet validated; rationale needed if development precedes IQ	§5.1
7	Development loop	Iterative (not linear) activities until an acceptable level of risk is reached	§5.2
8	Predetermined SBS specification	Development based on forming/assembly, seal, material and content requirements; families allowed with rationale	§5.3
9	Draft process specification	Process elements, production provisions, outputs and acceptance criteria identified and documented	§5.4
10	Initial process risk analysis	Failure modes, causes for all elements and provisions, variables and controls identified	§5.5
11	Process variables	Effects and upper/lower limits determined; parameters for validation selected	§5.6
12	Control and monitoring plans	Parameters, controls, monitored outputs, frequency, sample size, method, criteria and reaction plans documented	§5.7
13	Process specification and risk plan	Process specification established per ISO 11607-2; outputs support the risk management plan	§5.8–§5.9
14	Process equivalence	Alternate sealing equipment may leverage prior development if five conditions are met	Clause 6

3. Detailed Requirements and How to Comply

Clause 5 requires the process development activities in Figure 2 to be followed in an iterative way, not linearly, until the objective is achieved. Development concludes only when an acceptable level of risk has been reached; if not, the activities are reviewed and improved until it is.

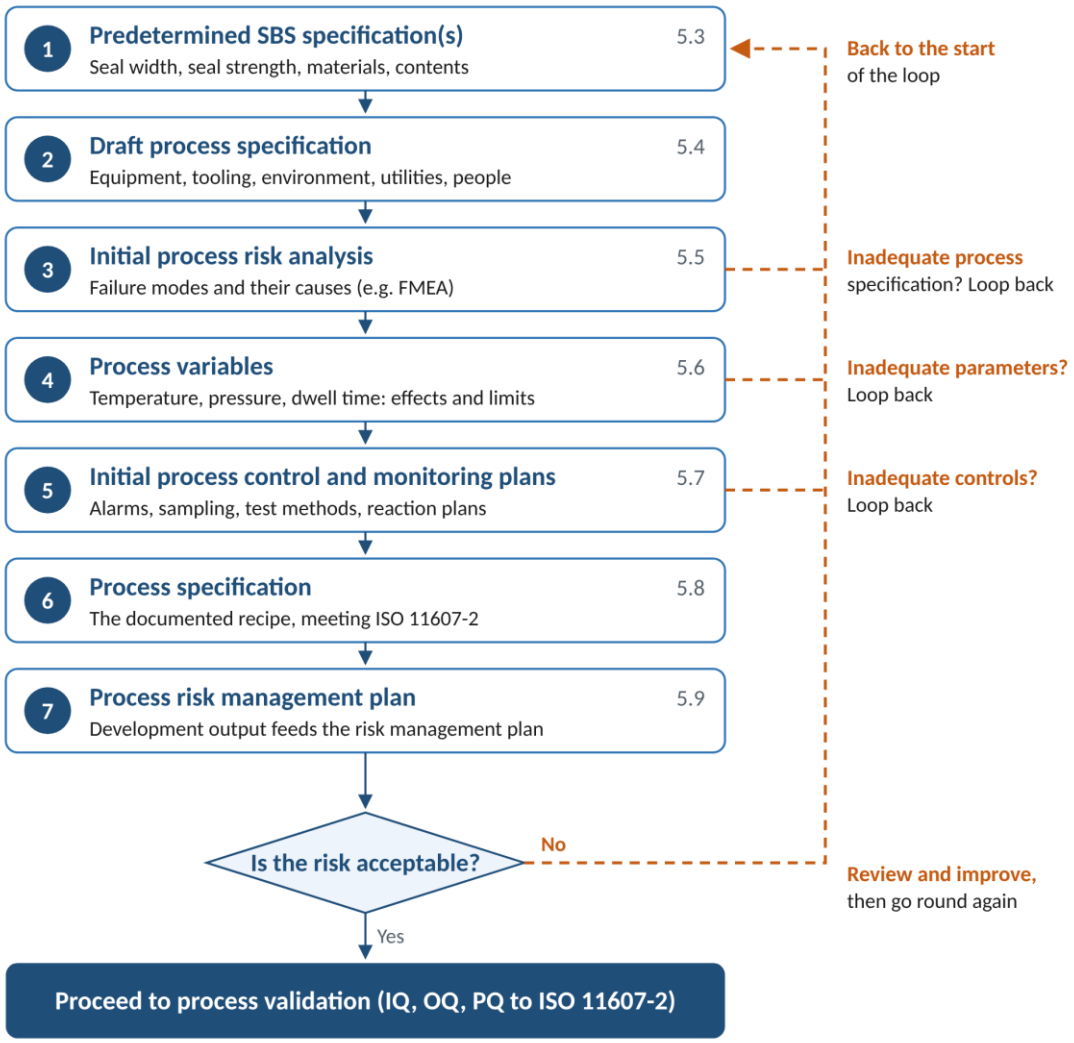


Figure 2 — Process development activities (based on Figure 1 of ISO 11607-3)

3.1 Scope and Applicability

ISO 11607-3 reference: Clause 1, §5.1 **Related guidance:** Annex C (equipment features)

ISO 11607-3 applies to heat-sealing processes that have not yet been validated. Seals of interest are those that establish a microbial barrier; seals used only for containment, and spot welds used to bond wraps, are excluded. Existing SBS and preformed SBS processes that have met the validation requirements of ISO 11607-2 are regarded as sufficient evidence that appropriate development has occurred. When development is carried out before installation qualification (IQ), a documented rationale should assess any risk to production equivalence and to process inputs and design outputs.

> **KEY REQUIREMENT (ISO 11607-3)**
> Apply the Clause 5 development process to every new heat-sealing process that creates a microbial barrier before it is validated. Already validated processes require no additional development work.

How to Comply?

- Build an inventory of all heat-sealing processes (pouch, bag, tray, FFS) and classify each as in scope (new / not yet validated) or out of scope (validated to ISO 11607-2, cold seal, containment seal).

- Record the classification and its justification in the validation master plan or packaging procedure.
- Where development is done on a lab or pre-IQ sealer, write a short rationale covering production equivalence and impact on process inputs and design outputs.

3.2 General Requirements: Quality, Risk, Sampling, Test Methods and Records

ISO 11607-3 reference: Clause 4 (§4.1–§4.5) **Related guidance:** ISO 11607-2:2019/Amd 1:2023

Clause 4 sets the ground rules. Development must take place within a formal quality system and follow the risk management process of ISO 11607-2/Amd 1:2023. Statistically valid sampling is required for validation; during development a statistical rationale is strongly recommended. Test methods must meet the validation requirements of ISO 11607-2, although preliminary evaluation methods (for example visual scoring of seals) may be used during development without validation. Documentation must meet ISO 11607-2:2019, 4.5.

> **KEY REQUIREMENT (ISO 11607-3)**
> Development activities shall be performed within a formal quality system, under an ISO 11607-2/Amd 1-compliant risk process, using validated test methods (preliminary methods excepted) and documented to ISO 11607-2 requirements.

How to Comply?

- Bring development protocols, raw data and reports under document and record control — not personal spreadsheets.
- Write a sampling rationale for development studies (materials, risks and SBS being evaluated), and keep validation sample sizes statistically justified.
- Validate seal strength (e.g. ASTM F88) and integrity test methods before relying on them; clearly label any preliminary method as such.

3.3 Predetermined SBS Specifications

ISO 11607-3 reference: §5.3 **Related guidance:** Annex B (heat sealing materials)

Process development starts from the package, not the machine. The predetermined SBS specification defines forming and assembly requirements (web overlap, freedom from wrinkles and creases, sequence of assembly), seal requirements (seal width, seal strength), packaging materials (trays, lids, preformed SBS, roll stock, retainers) and SBS contents. Development may be leveraged across families of similar SBSs or process specifications, provided the family rationale is documented.

> **KEY REQUIREMENT (ISO 11607-3)**
> Process development shall be based on predetermined SBS specification requirements. Where families are used, the rationale for the family shall be documented.

How to Comply?

- Approve the SBS specification (seal width, seal strength, materials, contents, assembly steps) before starting development runs.
- Use Annex B to understand the sealant system (sealant film vs heat seal coating; peelable vs weld seal) and the expected failure mode on peeling.

- Where a family approach is used, document the worst case and why other members are covered.

3.4 Draft Process Specification: Elements and Production Provisions

ISO 11607-3 reference: §5.4 **Related guidance:** Annex C

A well-developed sealing window is essential, but SBS integrity problems are often caused by what surrounds the sealer. The draft process specification identifies all process elements — equipment, accessories (heating plates, tooling, fixtures, gaskets, guides), measurement equipment, workflow equipment and consumables (seal jaw tape, mats, web cleaners) — and all production provisions: environmental conditions, utilities (compressed air, electrical supply), cleaning agents and disinfectants, installation, operation and maintenance procedures, personal protective equipment and personnel. Process outputs and acceptance criteria based on the SBS specification are documented.

> **KEY REQUIREMENT (ISO 11607-3)**
> Process elements and production provisions required to achieve the process outputs shall be identified, and the process outputs and acceptance criteria shall be documented in the process specification.

How to Comply?

- Create a standard 'process element and provision' checklist covering equipment, accessories, measurement, workflow, consumables, environment, utilities, cleaning, maintenance, PPE and people.
- Link each process output (seal width, seal strength, visual appearance, integrity) to an acceptance criterion taken from the SBS specification.
- Use the list as the scope for the risk analysis in §5.5.

3.5 Initial Process Risk Analysis

ISO 11607-3 reference: §5.5 **Related guidance:** Annex D (FMEA example); ISO 11607-2/Amd 1, Table B.1

The initial risk analysis asks what can go wrong and why. Typical failure modes are seal strength out of specification (weak or overly strong), narrow seals or voids, channels or open seals, damaged materials (punctures, tears, excessive melting) and unintended delamination of peelable seals. Typical causes are contamination of the seal tool or material (debris, cleaning residues, contaminated gloves), incorrect sealing equipment output (wrong settings, calibration offset, pneumatic loss, poor heat distribution), damaged process elements, incorrect tooling and incorrect set-up (web tension, alignment, line clearance). A previously documented analysis may be leveraged.

> **KEY REQUIREMENT (ISO 11607-3)**
> An initial process risk analysis shall identify failure modes, process-related causes for all process elements and production provisions, and the process variables and controls or monitoring needed to mitigate them.

How to Comply?

- Run an FMEA (Annex D) covering every element and provision from §5.4, not only the sealer settings.
- Rank failures by severity, occurrence and detection (RPN per IEC 60812); since severity rarely changes, reduce occurrence or improve detection.
- Map each cause to a control (e.g. cleaning procedure, calibration, alarm) or a monitored variable.

3.6 Process Variables and the Sealing Window

ISO 11607-3 reference: §5.6 **Related guidance:** Annex A (process parameters); Annex B

For heat sealing the key variables are temperature, contact pressure and dwell time (or line speed); the time between sealing cycles can also affect the output. Their effect on the outputs and their upper and lower limits must be determined, and the parameters for validation selected. Annex A recommends design of experiments (DOE), heat seal curve analysis (ASTM F2029) and visual scoring of seals, used alone or combined. Temperature is usually the most influential variable, followed by time and then pressure. Settings from a laboratory sealer can differ from production equipment settings. Figure 3 summarizes what happens on each side of the window.

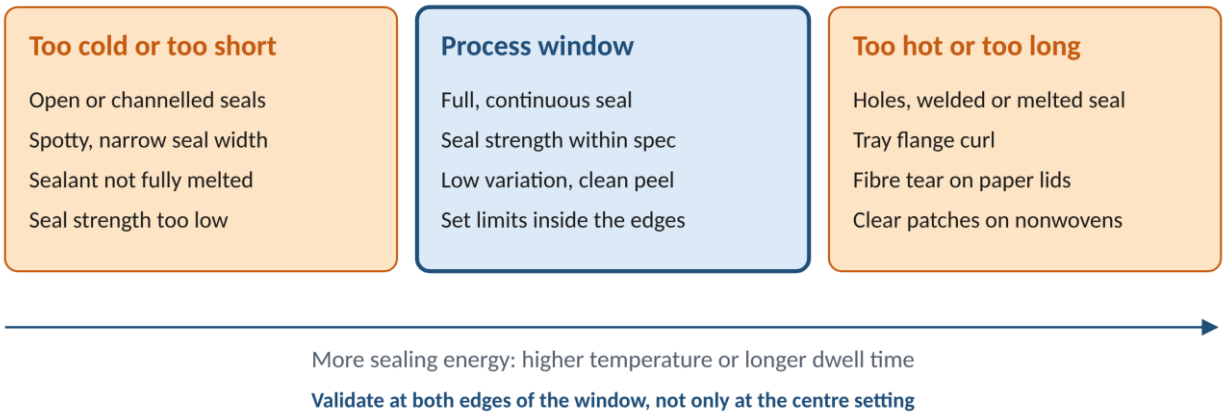


Figure 3 — The heat sealing window and the defects found on each side

Visual scoring at the low end of the sealing range (Table A.1 of ISO 11607-3) grades seals by how much of the specified seal width is properly formed:

Score	Visual seal observation at the low end of the range
0	Open seals
1	Spotty or non-homogeneous seal; seal width less than 50 % of the specified value
2	Spotty or non-homogeneous seal; seal width 50 % to 74 % of the specified value
3	Spotty or non-homogeneous seal; seal width 75 % to 94 % of the specified value
4	Seal width ≥ 95 % of the specified value with sporadic spotty areas
5	Full intended seal (≥ 95 %), fully continuous and homogeneous

KEY REQUIREMENT (ISO 11607-3)
The effect of the identified process variables on the outputs, and their upper and lower limits, shall be determined; process parameters to be used in validation shall be established.

How to Comply?

- Calibrate the sealer on site before development runs and record the offset between the display and the sealing surface (Annex C.2.1).
- Start with a screening DOE, then a more detailed study with centre points around the likely window.
- Build heat seal curves and score seals visually at both ends of the range (Tables A.1 and A.2); combine strength and visual score versus temperature to set limits well inside the edges.

3.7 Initial Process Control and Monitoring Plans

ISO 11607-3 reference: §5.7 **Related guidance:** Annex C (alarms, lock-outs, monitoring)

Knowing the window is not enough; the process must stay in it during production. The process parameters required to consistently meet the outputs are documented together with how they are monitored or controlled — sealing equipment can include systems to set, control and monitor variables, with alarms, warnings or machine stops when a variable exceeds its limits. For the outputs, the plan defines the monitoring frequency, sample size, test method, acceptance criteria and reaction plan. A control plan is a typical format.

> **KEY REQUIREMENT (ISO 11607-3)**
> Process parameters and the means of monitoring or controlling them, and the process outputs to be monitored (frequency, sample size, test method, acceptance criteria and reaction plans), shall be documented.

How to Comply?

- Prepare a control plan listing each parameter with its set point, tolerance and control (alarm, lock-out, interlock, monitoring).
- Define in-process checks for seal width, seal strength, visual quality and integrity with frequency, sample size and method.
- Write reaction plans telling operators exactly what to do when a parameter alarms or a test fails.

3.8 Process Specification and Process Risk Management Plan

ISO 11607-3 reference: §5.8, §5.9 **Related guidance:** ISO 11607-2:2019/Amd 1:2023, Annex B

The process specification pulls together the outputs of §5.4 to §5.7 into a documented procedure — one document or a series — that includes all equipment, process parameters, monitors and materials needed to manufacture a product that consistently meets requirements. It must be traceable to the predetermined design specification and is the basis for process validation. The outputs of development also support the process risk management plan; Amendment 1 to ISO 11607-2 permits combining packaging risk management records with those of the medical device.

> **KEY REQUIREMENT (ISO 11607-3)**
> The process specification shall be established from the outputs of §5.4 to §5.7 and meet ISO 11607-2; development outputs shall support the risk management plan, and development concludes only when the risk is acceptable.

How to Comply?

- Issue a controlled process specification traceable to the SBS specification before IQ/OQ/PQ protocols are approved.
- Update the risk management file with the development results and record the decision that the residual risk is acceptable.
- Loop back (Figure 2) whenever the specification, parameters or controls are found inadequate.

3.9 Process Equivalence for Alternate Sealing Equipment

ISO 11607-3 reference: Clause 6 **Related guidance:** Annex E (statistical equivalence)

Clause 6 provides a documented route to avoid repeating development when deploying alternate equipment — new, used or refurbished machines, or machines moved to a new location (for example a site with a different electrical power system). All five conditions in Figure 4 must be met. Alternate equipment may need different settings to deliver the same sealing energy; the test is whether the output meets the SBS specification. Annex E recommends statistical comparison of seal strength, typically with a TOST (two one-sided t-tests) equivalence test against a justified zone of equivalence, preferably using production monitoring data at nominal settings.

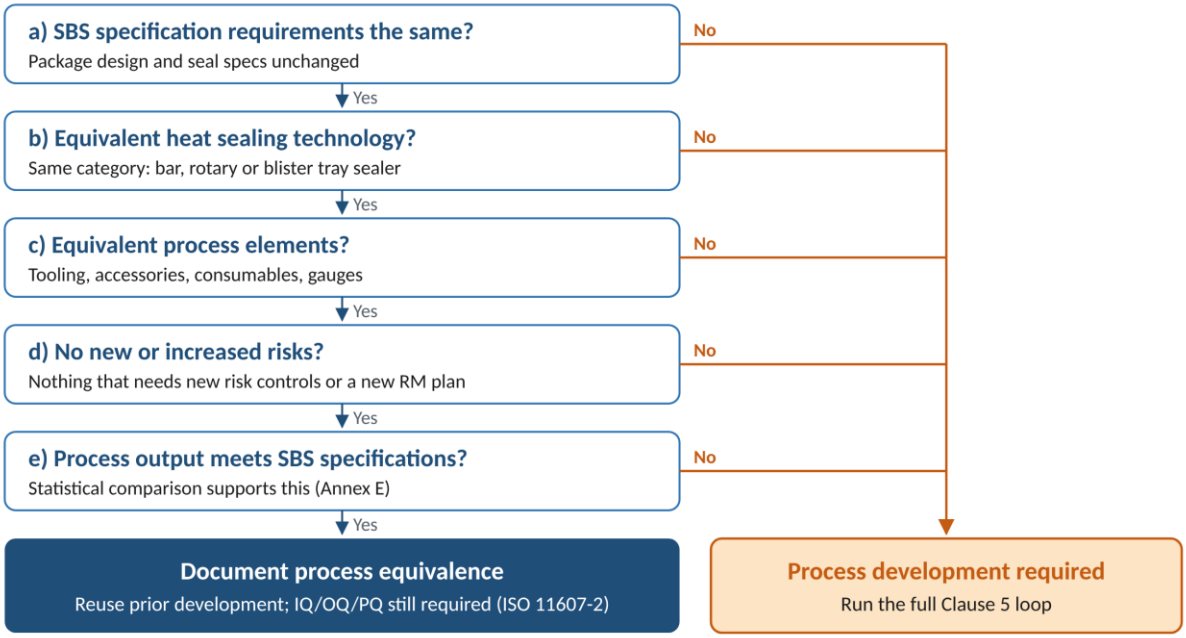


Figure 4 — Process equivalence decision tree (based on Figure 2 of ISO 11607-3)

KEY REQUIREMENT (ISO 11607-3)
Processes on alternate sealing equipment may be considered equivalent only if the SBS specification is the same, the sealing technology and process elements are equivalent, no new or increased risks are introduced, and outputs meet the SBS specification. Validation on the alternate equipment remains required.

How to Comply?

- Write an equivalence procedure with the five-question checklist and the statistical method, including how the equivalence limits are justified.
- Use the same material lot and the same seal strength test method when comparing machines (Annex E.3, E.4).
- Perform IQ, OQ and PQ on the alternate equipment under change control; prior ISO 11607-1 Clause 8 testing remains valid (6.3).

3.10 Heat Sealing Equipment Features

ISO 11607-3 reference: Annex C (informative) **Related guidance:** ISO 11607-2:2019, 5.2

Annex C recommends minimum equipment features that support validation, control and monitoring. Temperature should be uniform across the sealing surface and stable at set point; contact pressure should be uniform with

parallel jaws and compressible gaskets, and force output should be assessed because it varies between machines of the same model; dwell time or line speed should be monitored. For each variable the equipment should alarm and lock out outside the set window. Calibration should be done on site, as part of or before IQ, without removing sensor modules, and equipment that cannot be calibrated should not be used. Seal surfaces should be accessible for maintenance and free of sharp edges that could damage the SBS.

> **KEY REQUIREMENT (ISO 11607-3)**
> Heat sealing equipment that is not capable of being calibrated should not be used. Equipment should monitor, alarm and lock out on temperature, pressure and dwell time outside the validated window.

How to Comply?

- Add Annex C features (monitoring, alarms, lock-outs, calibration ports, parallel jaws, cleanable seal surfaces) to sealer purchase specifications.
- Establish on-site calibration and recalibration schedules; recalibrate before any revalidation.
- Assess the calibration offset and the pneumatic force output of each machine and consider them in validation.

4. Compliance Action Plan — What to Do in Real Life to Comply

Complying with ISO 11607-3 means running every new heat-sealing process through a written, risk-based development routine before validation, and keeping the records that prove it. In practice this comes down to ten actions in two stages.

4.1 Set It Up Before You Seal

- **Map your sealing processes.** List every heat-sealing process (pouch, tray, FFS). New or not yet validated processes are in scope; processes validated to ISO 11607-2 are already covered (5.1.1).
- **Write one development procedure.** Add a sealing process development SOP that follows the Clause 5 loop and states that validation does not start until the risk is acceptable.
- **Freeze the package specification first.** Seal width, seal strength, materials, contents and assembly steps are written and approved before any development run.
- **List everything that touches the seal.** Tooling, gaskets, seal jaw tape, web cleaners, gauges, conveyors, room conditions, inspection lighting, compressed air, power, cleaning agents, gloves and gowns, maintenance and operator training. This becomes the draft process specification.
- **Run a real risk analysis.** An FMEA covering failures (weak or strong seals, channels, voids, tears, delamination) and causes (dirty jaws, residues, calibration offset, air pressure loss, worn gaskets, wrong tooling, poor web tension), with each cause tied to a control.

4.2 Prove It, Write It, Keep It

- **Prove the sealing window with data.** Calibrate on site, record the offset, run DOE, build heat seal curves and score seals at both ends of the range; set limits inside the edges.
- **Write the control plan.** For each parameter, how it is controlled; for each output, the frequency, sample size, validated method, pass criteria and reaction plan.
- **Issue the process specification and update the risk file.** One controlled document set, traceable to the SBS specification. Then perform IQ, OQ and PQ to ISO 11607-2.

- **Set up an equivalence route for new sealers.** A procedure built on the five Clause 6 checks and a statistical seal strength comparison (e.g. TOST).
- **Buy equipment you can control.** Calibratable sensors for temperature, pressure and dwell time, alarms and lock-outs, even heating, parallel jaws and cleanable seal surfaces in every purchase specification.

4.3 When Is Process Development (and Is It Not) Required

Process development should be driven by a documented assessment, not applied blanket-wide. The table below summarizes when the full Clause 5 loop is required.

Scenario	Process Development Required?	Rationale
New heat-sealing process for a new or changed SBS, not yet validated	Yes — full Clause 5 loop	Core scope of ISO 11607-3 (§5.1.1)
Existing heat-sealing process already validated to ISO 11607-2	No	Validation is regarded as sufficient evidence of development (§5.1.1)
Additional sealer of the same technology category for the same SBS	No — if equivalence is documented	Prior development may be leveraged (§6.2); IQ/OQ/PQ still required
Sealer moved to a new location or a different power system	Equivalence assessment	Covered by ‘alternate’ equipment (§6.1, Note 1)
Different sealing technology (e.g. bar sealer replaced by rotary sealer)	Yes	Fails the equivalent technology condition (§6.1 b)
New SBS within a documented family	Leverage with documented rationale	Families of similar SBS are allowed (§5.3.2)
Change to SBS materials, seal width or seal strength specification	Yes, plus ISO 11607-1 change management	SBS specification no longer the same (§6.1 a)

4.4 Common Pitfalls and How to Avoid Them

The following mistakes are the most common causes of failed or fragile sealing validations, and are exactly what a structured ISO 11607-3 development process prevents.

Pitfall	Why It Hurts	What to Do Instead
Validating at one 'golden' setting	A seal that works only at the centre fails when the sealer drifts	Map the window and challenge both edges (§5.6, Annex A)
Copying lab sealer settings to production	Lab heat seal curves come from a different, calibrated device	Use lab curves as guidance; confirm on the production sealer
Trusting the display temperature	The calibration port can differ from the sealing surface	Assess the calibration offset and use it in validation (C.2.1)
Assuming equal pressure settings give equal force	Force output varies even between identical models	Measure the force output of each sealer (C.3.3)
Looking only at the sealer	Contamination, tooling, web tension or air supply cause many failures	Include all elements and provisions in the risk analysis (§5.4, §5.5)
Judging seals on strength alone	Strong seals can still have holes, curl or fibre tear	Combine strength testing with visual scoring (A.2.4)

5. Regulatory Audit Q&A Takeaways

The following structured responses are provided for use when an internal or external auditor, notified body or inspector asks how a heat-sealing process was developed.

Auditor Question / Scenario	Recommended Technical Response
How was this sealing process developed before validation?	Per our sealing process development SOP, which follows ISO 11607-3 Clause 5: approved SBS specification, draft process specification, initial risk analysis, DOE on process variables, control and monitoring plan and final process specification. The records are referenced in the validation master plan.
How were the validated parameters and their limits chosen?	From DOE, heat seal curves and visual scoring at both ends of the range (Annex A). Validation settings sit inside the window with margin from the failure edges; the development report shows the data.
Is the temperature you validated the real temperature at the seal?	The sealer was calibrated on site before development and IQ. The offset between the calibration port and the sealing surface was assessed and considered in validation (Annex C.2.1, C.5).
This process predates ISO 11607-3. Is that a gap?	No. Processes that met the validation requirements of ISO 11607-2 are regarded as sufficient evidence of development (§5.1.1). New processes follow the ISO 11607-3 procedure.
You added a second sealer. Why was development not repeated?	Equivalence was documented per Clause 6: same SBS specification, same sealer category, equivalent process elements, no new risks, and outputs meeting specification, supported by a TOST seal strength comparison. IQ/OQ/PQ was performed on the new sealer.
What stops production running outside the window?	The control plan (§5.7): alarms and lock-outs on temperature, pressure and dwell time, in-process seal checks at defined frequency and sample size, and documented reaction plans.

6. Conclusions and Recommendations

- ISO 11607-3:2026 is the missing step between package design (ISO 11607-1) and process validation (ISO 11607-2). It defines how to develop a heat-sealing process so that validation becomes a confirmation rather than a gamble.
- Development starts from the predetermined SBS specification and follows an iterative loop — draft specification, risk analysis, variables, controls, process specification — until the risk is acceptable.
- The sealing window must be established with data (DOE, heat seal curves, visual scoring), and validated settings must sit well inside its edges.
- The process is more than the sealer: people, cleaning, utilities, tooling and environment must be included in the risk analysis and controls.
- Clause 6 equivalence allows new, moved or refurbished sealers to leverage prior development, while IQ/OQ/PQ remains required. Already validated processes need no additional development work.
- Manufacturers are encouraged to complete the compliance checklist in the Appendix, pilot the procedure on one upcoming sealing process, and check whether their regulator or notified body formally recognizes this edition.

References

1. ISO 11607-3:2026, Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly.

2. ISO 11607-1:2019, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.

3. ISO 11607-2:2019 and Amd 1:2023, Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes.

4. ISO 11139:2018, Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards.

5. ISO/TS 16775:2021, Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2.

6. IEC 60812, Failure modes and effects analysis (FMEA and FMECA).

7. ASTM F88/F88M, Standard test method for seal strength of flexible barrier materials; ASTM F1886/F1886M, Standard test method for determining integrity of seals by visual inspection; ASTM F2029, Standard practices for making laboratory heat seals.

8. EN 868-5:2018, Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction.

9. Meyners M., Equivalence tests — A review. Food Quality and Preference, 2012, 26(2), pp. 231–245.

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ISO 11607-3:2026 Compliance Checklist

This checklist provides a clause-by-clause compliance review against ISO 11607-3:2026, 'Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly'. For each requirement, the gap impact, the action required and the evidence an auditor will expect are listed together with a suggested priority. This checklist should be completed and maintained by the Quality Unit as a living record of the implementation program.

Priority: High – address before next validation / audit | **Medium – address within implementation program** | **Low – administrative / documentation update**

#	ISO 11607-3 Clause	Topic	Requirement	Gap Impact if Unaddressed	Action Required to Close the Gap	Evidence for Auditor	Priority
1	§4.1	Quality system	Development performed within a formal quality system	Development data not controlled; cannot support validation	Bring development protocols, data and reports under QMS document and record control	QMS procedures; controlled development records	**High**
2	§4.2	Risk management	Risk process conforming with ISO 11607-2/Amd 1:2023	Risk decisions undocumented or inconsistent	Align packaging risk procedure with Amd 1 Annex B; combine with device file if desired	Risk management procedure and file	**High**
3	§4.3	Sampling	Statistically valid sampling for validation; rationale recommended in development	Sample sizes challenged by auditors	Document sampling rationale for development and validation studies	Sampling rationale	**Medium**
4	§4.4	Test methods	Methods validated per ISO 11607-2; preliminary methods allowed in development	Data from unvalidated methods rejected	Validate seal strength and integrity methods; label preliminary methods	Test method validation reports	**High**
5	§4.5	Documentation	Records per ISO 11607-2:2019, 4.5	Incomplete development record	Define development record set in the SOP	Development file index	**Medium**
6	§5.1	Scope	Apply to processes not yet validated; rationale if development precedes IQ	Wrong processes developed or skipped	Inventory and classify all sealing processes; write pre-IQ rationale	Process inventory; rationale	**Medium**
7	§5.2	Development loop	Iterative activities until risk is acceptable	Validation starts on an immature process	Write development SOP following the Clause 5 loop with a risk acceptance gate	Development SOP; risk acceptance record	**High**
8	§5.3	SBS specification	Development based on predetermined SBS specification; family rationale documented	Process built to undefined targets	Approve SBS specification before development; document families	Approved SBS specification; family rationale	**High**

#	ISO 11607-3 Clause	Topic	Requirement	Gap Impact if Unaddressed	Action Required to Close the Gap	Evidence for Auditor	Priority
9	§5.4	Draft process specification	Process elements, production provisions, outputs and acceptance criteria documented	Failures from surroundings of the sealer missed	Use an element / provision checklist; link outputs to criteria	Draft process specification	**Medium**
10	§5.5	Initial risk analysis	Failure modes, causes for all elements and provisions, variables and controls identified	Uncontrolled causes of seal failure	Run FMEA covering all elements and provisions; tie causes to controls	FMEA with actions	**High**
11	§5.6	Process variables	Effects and limits determined; validation parameters selected	Validation at a single fragile setting	DOE, heat seal curves and visual scoring at both ends of the range	DOE report; heat seal curves; scoring records	**High**
12	§5.7	Control and monitoring	Parameters, controls, monitored outputs, frequency, sample size, method, criteria, reaction plans	Drift outside the window not detected	Issue a control plan with reaction plans	Control plan	**High**
13	§5.8	Process specification	Established from §5.4–§5.7, meets ISO 11607-2, traceable to design	No defined basis for validation	Issue controlled process specification before IQ/OQ/PQ	Process specification	**High**
14	§5.9	Risk management plan	Development outputs support the risk management plan	Risk file not updated	Update risk file with development results	Updated risk management plan	**Medium**
15	Clause 6	Process equivalence	Five conditions met for alternate equipment; validation still required	Unjustified reuse or unnecessary repeat development	Write equivalence procedure and checklist	Equivalence assessment; IQ/OQ/PQ reports	**Medium**
16	Annex E	Statistical equivalence	Statistical comparison of seal outputs (e.g. TOST)	Equivalence claims unsupported	Define TOST method and justified equivalence limits	Statistical comparison report	**Low**
17	Annex C.5	Calibration	On-site calibration; non-calibratable equipment not used	Validated settings do not reflect reality	Calibrate on site before IQ; set recalibration schedule	Calibration certificates; offset records	**High**
18	Annex C.2–C.4	Equipment features	Monitoring, alarms and lock-outs for temperature, pressure, dwell time	Out-of-window sealing undetected	Add Annex C features to purchase specifications	Equipment URS / purchase specification	**Medium**

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