ISO 13485 Production and Service Controls Readiness Checklist

Elexes

An initial self-assessment against clause 7.5 of ISO 13485:2016, with links to 4.1.6 and 6.4. FDA's QMSR also applies these clauses in the US from February 2, 2026. Tick an item only if you can show a controlled record for it.

Production control — 7.5.1

- [ ] Documented procedures, work instructions and methods cover each production step.
- [ ] Infrastructure and equipment are qualified before use.
- [ ] Process parameters and product characteristics are monitored, with defined release criteria.
- [ ] A record for each device or batch shows the quantity made and approved for distribution.

Cleanliness and contamination — 7.5.2 · 6.4

- [ ] You have determined which clause 7.5.2 cleanliness conditions apply to your product.
- [ ] Cleaning requirements and removal of process agents are documented where applicable.
- [ ] Work environment and contamination controls are defined where product needs them.
- [ ] Cleaning processes whose results aren't verified afterwards are validated.

Installation and servicing — 7.5.3 · 7.5.4

- [ ] Installation acceptance criteria and verification requirements are documented where applicable.
- [ ] Installation and verification records are kept, including for third-party installers.
- [ ] Servicing procedures, reference materials and reference measurements are documented where needed.
- [ ] Servicing records are analyzed for complaints and as input to improvement.

Identification and traceability — 7.5.8 · 7.5.9

- [ ] Product and its inspection status are identified throughout production.
- [ ] Returned product is identified and kept separate from conforming product.
- [ ] A UDI is applied and recorded where regulations require it.
- [ ] Traceability records are defined; implantables cover components, materials, environment and distribution.

Sterile devices and sterilization — 7.5.5 · 7.5.7

- [ ] Sterilization parameters are recorded for each sterilization batch and traced to production batches.
- [ ] Sterilization processes are validated to the applicable standard before use.
- [ ] Sterile barrier systems are validated, for example against ISO 11607.
- [ ] The need to revalidate is assessed after product, process or supplier changes.

Process and software validation — 7.5.6 · 4.1.6

- [ ] Processes whose output isn't verified afterwards are identified and validated.
- [ ] Protocols set acceptance criteria, equipment and personnel qualification, and sample-size rationale.
- [ ] IQ, OQ and PQ (or equivalent) results are approved and linked to risk management.
- [ ] Production and QMS software is validated before first use and after changes, in proportion to risk.

Preservation and customer property — 7.5.11 · 7.5.10

- [ ] Packaging and shipping containers protect product through storage, handling and distribution.
- [ ] Special conditions such as temperature limits are documented and controlled.
- [ ] Preservation also covers constituent parts of the product.
- [ ] Customer property is identified, verified and protected, and any loss or damage is reported.

Found gaps?

Elexes can remediate procedures, plan validation and prepare records for FDA, EU MDR, UK, Health Canada and TGA expectations.

www.elexes.com

Disclaimer: This checklist is an initial readiness tool and does not replace regulatory assessment, certification, legal advice, or authority review.

References: ISO 13485:2016, clauses 4.1.6, 6.4 and 7.5; 21 CFR Part 820 (QMSR), effective February 2, 2026; Regulation (EU) 2017/745.