A WORKING GUIDE

The *Sixty* Documents.

A practical walk through the documentation set that takes a medical device from *concept* to *repeatable manufacture* — and the places where most teams quietly start to slip.

Written by the team at IntelliDesign — high-reliability electronics design and manufacture, certified to ISO 13485, for founders, product leads and engineering managers.

I.
CONTENTS

A guide, not a checklist. Start at the beginning, or jump to the stage you are in.

§ CONTENTS · WHAT IS IN THIS GUIDE

Eleven sections. Seven stages. Roughly sixty documents.

The number is not the point. The *connectedness* is.

01

WHY IT MATTERS
THE THESIS

A device is finished when there is enough evidence to defend it – not when it works on the bench.

§ 01 WHY THE DOCUMENTATION SET MATTERS

A medical device is not finished when it works.

It is finished when there is enough evidence — drawn, written, signed and *connected* — to show how it came to work, why it can be trusted to keep working, and how the next unit off the line will be the same as the one a reviewer holds in their hand.

That evidence accumulates as documents. Plans, specifications, traceability matrices, protocols, reports, records, files and approvals. By the time a typical Class II device reaches release, a project will have produced somewhere in the region of sixty of them – give or take, depending on classification, software content, manufacturing model and regulatory pathway.

Most teams do not think about the documentation set early enough. The product is exciting. The clinical opportunity is urgent. The first prototype works, and the assumption is that the paperwork will fall in behind it. It rarely does. By the time the team needs to verify against requirements that were never written down, or validate with users that were never defined, or transfer to a manufacturer using drawings that do not match the build, the cost of repair is no longer a few weeks of writing. It is months of rework, repeated testing, and difficult conversations with investors and regulators.

The strongest design history files are not the ones with the most documents. They are the ones where every document can be traced to the decision it supports.

– THE THESIS OF THIS GUIDE

This guide is a walk through the set. It explains what each major document does, how the stages connect, where teams most often get into trouble, and what a regulator, notified body or experienced consultant will actually look for when they pick a file off the shelf.

It is not a substitute for a quality management system, regulatory advice, or the underlying standards – ISO 13485, ISO 14971, IEC 62366, IEC 62304, EU MDR, FDA 21 CFR Part 820 and their relatives. Think of it instead as a map of the territory, written for the people who have to walk it.

02

THE SEVEN STAGES

AT A GLANCE

Each stage produces records that feed the next. Break the chain at any point and traceability is lost downstream.

§ 02 THE SEVEN STAGES

The pathway, at a glance.

The same shape applies to almost every device project, from a single-use disposable to a connected platform. What differs is the depth at each stage.

I. Strategy & Planning ~10 DOCUMENTS	II. User Needs & Inputs ~7 DOCUMENTS	III. Risk Management ~6 DOCUMENTS	IV. Design Outputs ~9 DOCUMENTS	V. Verification ~9 DOCUMENTS	VI. Validation & Usability ~6 DOCUMENTS	VII. Transfer & Release ~13 DOCUMENTS
Intended use	Pre-study report	Preliminary hazard analysis	Mech. drawings	Verification protocols / records	Formative protocol & records	Manufacturing flowchart
Regulatory strategy	Use specification	Task analysis	Component specs	Functional testing	Summative protocol & records	Process spec & URS
D&D plan (scope / schedule / budget)	Traceability — user needs	UI evaluation plan	Electronic schematics	Electrical safety	Validation protocols / records	IQ / OQ / PQ plans & reports
Software plan	Traceability — design inputs	Hazard traceability matrix	Gerber files	Biological evaluation	Clinical evaluation report	In-process controls
Risk mgmt plan	System design description	P-FMEA	Assembly drawings	Shelf-life		Receiving inspection
Verification & transfer planning	SW safety classification	Risk management report	Raw material specs	V&V summary report		Production units / DHR
	SW architecture		SW detailed design			Design transfer checklist
			Source & compiled code			GSPR checklist
						Declaration of conformity

The diagram above is deliberately a count, not a network. The real map is denser — most of these documents reference one or more others, and the same artefact (a traceability matrix, a risk file, a master validation plan) is revisited across multiple stages as the design matures. Treat the stages as *checkpoints*, not phases. A team rarely does Stage 1 once and finishes it.

I.

STAGE ONE

STRATEGY & PLANNING

The documents that decide what you are building, why, and how the team will prove it later.

STAGE I · STRATEGY & PLANNING

Decide the shape of the project before you commit to its drawings.

The first stage looks deceptively administrative. It is not. The decisions made here — about intended use, regulatory pathway, safety classification, schedule and budget — quietly determine what every later document has to contain.

Most expensive surprises in a medical device project are traceable to a Stage 1 document that was either skipped or written too loosely. An intended use statement that quietly drifts during development changes the device's risk class. A regulatory strategy chosen without checking equivalent devices triggers an extra clinical investigation late in the timeline. A software plan that misclassifies the device's safety class doubles the verification workload. None of these are visible in the build. All of them are visible in the file.

The point of this stage is to write the project's commitments down clearly enough that everything downstream can be measured against them. If the team cannot describe the device, its users, its environment, its classification and its development plan in writing, it is too early to start drawing parts.

01	Pre-study report – *evidence base, equivalents, predicate analysis*	• REQUIRED
02	Intended use statement – *the foundation of the entire file*	• REQUIRED
03	System design description *(tentative)* – *first technical sketch*	• REQUIRED
04	Use specification – *users, environment, workflow, contraindications*	• REQUIRED
05	Regulatory strategy – *pathway, classification, target markets*	• REQUIRED
06	Standards & norms list – *applicable harmonised standards*	• REQUIRED
07	Design & development plan – *scope, schedule, budget (three artefacts)*	• REQUIRED
08	Software development plan – *per IEC 62304*	○ IF SOFTWARE
09	Risk management plan – *per ISO 14971*	• REQUIRED
10	Verification & design transfer planning – *planned now, executed later*	• REQUIRED

• REQUIRED FOR MOST DEVICE PROJECTS ○ CONDITIONAL ON TECHNOLOGY, CLASS OR PATHWAY

WHERE TEAMS STUMBLE

The intended use is treated as marketing copy rather than a regulatory anchor. It changes between investor decks, clinical materials and the technical file. Every downstream document inherits the ambiguity – and by Stage 6, it becomes impossible to say whether the device was validated against the use it actually claims.

The development plan exists, but is not living. It was written once, signed, and filed. The schedule slipped four months ago; the plan does not reflect that. Design reviews scheduled in the plan never happened.

HOW WE PARTNER AT THIS STAGE

Most of our projects start here. There is a pre-study, a intended use is drafted, regulatory pathway chosen, and a design controls framework is created for the rest of the development to run on. From that point we work closely with our customers and lead the engineering ourselves. The plan is built once, properly, and survives the next eighteen months without being rewritten.

TALK TO US ABOUT CONCEPT & PLANNING →

II.

STAGE TWO

USER NEEDS &
DESIGN INPUTS

Turning the product idea into measurable requirements that can be verified – and traced – later.

Vague requirements are the most expensive thing you can write.

User needs describe what the device must achieve for the people it serves. Design inputs translate those needs into measurable requirements. *Measurable* is doing the work in that sentence.

A requirement that reads "the device shall be easy to use" is unverifiable. A requirement that reads "the device shall be operable, end-to-end, by a registered nurse with no prior training, in under ninety seconds, in summative usability testing, with no use errors classified as critical" is verifiable. The difference between those two sentences is roughly six months of project time, in the right direction.

The traceability matrix introduced at this stage is not paperwork. It is the structural beam of the design history file. Every user need links to one or more design inputs. Every design input links to a verification activity. Every risk control links back to the requirement it implements. When a regulator or notified body opens the file, they navigate by this matrix. When the matrix is missing or broken, the file collapses regardless of how good the underlying engineering was.

11	Requirement traceability matrix – *user needs*	• REQUIRED
12	Requirement traceability matrix – *design inputs*	• REQUIRED
13	Requirement traceability matrix – *verification & validation plans*	• REQUIRED
14	System design description – *the device, defined*	• REQUIRED
15	Software safety classification – *Class A / B / C per IEC 62304*	○ IF SOFTWARE
16	Software architecture – *items, interfaces, SOUP*	○ IF SOFTWARE
17	Sub-system requirement specifications – *mechanical, electrical, software, packaging*	• REQUIRED

WHERE TEAMS STUMBLE

The traceability matrix is built once and never maintained. New requirements are added in engineering tickets and design reviews, but the matrix lags by three sprints. By the time verification begins, the engineering team and the regulatory team are working from different requirement sets.

Design inputs include performance and functional requirements but omit environmental, packaging, service, cybersecurity or interface requirements. The omissions surface during verification planning, when nobody can find an acceptance criterion to test against.

HOW WE PARTNER AT THIS STAGE

Our engineers translate user needs into measurable design inputs as a normal part of how we develop devices — not as a separate documentation exercise. The traceability matrix is built into the project's tooling from the first sprint, owned by the engineering lead, and maintained as the design changes rather than reconstructed at the end.

TALK TO US ABOUT REQUIREMENTS & TRACEABILITY →

III.

STAGE THREE

RISK MANAGEMENT

A live, connected file – not a one-off deliverable.

STAGE III · RISK MANAGEMENT

Risk management is a verb, not a deliverable.

The risk file is the only document in the project that should never reach a final version until the device is retired. Everything else has a sign-off page; the risk file has a revision history.

ISO 14971 expects risk to influence design decisions, requirements, verification activities, labelling, instructions for use, and post-market surveillance. In practice, this means that the hazard analysis, the P-FMEA, the use-related risk analysis and the traceability matrix have to share a vocabulary and a structure. When they don't – when hazards are written one way in the risk file and another in the verification protocols – the team cannot defensibly show that a known hazard was controlled.

The hazard traceability matrix solves this. It is the second backbone document of the file, alongside the requirement traceability matrix. Every hazard links to its risk controls; every risk control links to the design output that implements it and the verification activity that confirms it works. A reviewer should be able to pick any hazard from the analysis and walk it to a test report in two clicks.

18	Preliminary hazard analysis – *first pass, written early*	• REQUIRED
19	Task analysis – *use-related, per IEC 62366-1*	• REQUIRED
20	User interface evaluation plan – *formative & summative scope*	• REQUIRED
21	Hazard traceability matrix – *hazards → controls → evidence*	• REQUIRED
22	Process FMEA – *or equivalent process risk analysis*	• REQUIRED
23	Risk management report – *overall residual risk, benefit-risk conclusion*	• REQUIRED

WHERE TEAMS STUMBLE

The risk file is owned by a single person, often a contractor, and lives in a separate spreadsheet that nobody else updates. When the device changes, the risk file does not. The mismatch surfaces during the final risk management review, six weeks before submission.

Use-related risk is treated as a usability problem, not a risk problem. Risks introduced by the user interface – wrong button presses, misread labels, missed alarms – are not linked to design controls. Summative usability then surfaces hazards that the risk file does not contain.

HOW WE PARTNER AT THIS STAGE

Because we own the design as well as the file, our risk work informs the engineering rather than chasing it. Hazard analyses, FMEAs and use-related risk run alongside concept and prototype development – and where we are brought in late, we rebuild risk files that have drifted from the design they were meant to control.

TALK TO US ABOUT RISK MANAGEMENT →

IV.

STAGE FOUR

DESIGN OUTPUTS

Where the device stops being an idea and starts being a part number.

STAGE IV · DESIGN OUTPUTS & TECHNICAL DOCUMENTATION

The design history file becomes a build package.

Design outputs are what a contract manufacturer needs to make the device, what an inspector needs to check it, and what a regulator needs to confirm that the thing you tested is the thing you ship.

The discipline at this stage is consistency. Drawings, schematics, bills of materials, source code, supplier records and inspection criteria all describe the same device. When they describe slightly different devices — because the BOM was updated but the assembly drawing was not, or because the firmware version in the test record does not match the version in the release — verification activities become unfalsifiable. A reviewer cannot tell which version of the device passed the test.

Software work runs in parallel and follows its own structure, defined by IEC 62304. A detailed design description and the source code are the conventional outputs; the less obvious ones are the SOUP justification, anomaly list and configuration management records, which auditors increasingly ask for first.

24	Mechanical drawings — *controlled, revision-numbered*	• REQUIRED
25	Component specifications	• REQUIRED
26	Electronic schematics	○ IF ELECTRONIC
27	Gerber & PCB design files	○ IF ELECTRONIC
28	Assembly drawings & work instructions	• REQUIRED
29	Raw material specifications	• REQUIRED
30	Software detailed design description — *per IEC 62304*	○ IF SOFTWARE
31	Source code — *under configuration control*	○ IF SOFTWARE
32	Compiled / released build artefact — *hash-identified*	○ IF SOFTWARE

WHERE TEAMS STUMBLE

Drawings exist but are not under document control. Revisions are tracked in the file name. Two drawings of the same part, dated weeks apart, both look authoritative and disagree about a tolerance.

Software outputs are managed by engineering tools (git, Jira, CI), but the link between a tested build and a released device is informal. A reviewer asks which firmware was on the units used for biological evaluation, and nobody can answer with certainty.

HOW WE PARTNER AT THIS STAGE

Design outputs are our home discipline. Mechanical, electronics, firmware and application software are produced by our engineers under document and configuration control from the first revision — so the design history file accumulates correctly as a side-effect of the work, not as a separate clean-up after it.

TALK TO US ABOUT ENGINEERING & TECHNICAL FILES →

V.

STAGE FIVE

VERIFICATION

"Did we build it correctly?" – the answer is a paper trail, not an opinion.

STAGE V · VERIFICATION

Verification is a question of evidence, not confidence.

Verification asks: *did we build the device correctly, against the requirements we wrote down?* Confidence in the bench result is not enough. The reviewer wants the protocol, the acceptance criterion, the raw data, the analysis, the report and the link back to the requirement.

The strength of a verification file is set in Stage 2. If requirements are measurable, protocols write themselves; acceptance criteria are obvious; results are unambiguous. If requirements are vague, protocols become creative writing exercises and acceptance criteria are invented during testing – which a careful reviewer can usually tell.

Specialist verification streams – electrical safety to IEC 60601, biocompatibility under ISO 10993, software verification under IEC 62304, accelerated aging and shelf-life – typically involve third-party laboratories. The job of the in-house team is to define what is being tested, ensure the device under test matches a controlled configuration, and integrate the lab's report into the design history file with a clear pointer from the requirement to the result.

33	Verification protocols – *per requirement family*	● REQUIRED
34	Verification records – *raw data, signed*	● REQUIRED
35	Functional testing protocol & record	● REQUIRED
36	Electrical safety testing protocol & record – *IEC 60601 family*	○ IF ELECTRICAL
37	Biological evaluation protocol & record – *ISO 10993*	○ IF PATIENT-CONTACTING
38	Shelf-life verification protocol & record – *accelerated & real-time*	● REQUIRED
39	Software verification records – *unit, integration, system*	○ IF SOFTWARE
40	Verification & validation summary report – *bridging document*	● REQUIRED

WHERE TEAMS STUMBLE

Test reports exist as PDFs from the lab, but there is no in-house protocol that defines what was sent and why. The requirements they verify are not named in either the protocol or the report. The link has to be reconstructed after the fact, often badly.

The device under test in the verification report is not the device that will be released. A component changed, a firmware was updated, a supplier was qualified later – and nobody flagged that the verification needs to be re-run or formally bridged.

HOW WE PARTNER AT THIS STAGE

We plan and run verification in-house wherever we can, and manage the third-party labs end-to-end where we cannot — electrical safety, biocompatibility, accelerated aging. The output we care about most is the V&V summary report: the single document that turns dozens of test records into a defensible argument that the device meets its requirements.

TALK TO US ABOUT VERIFICATION →

VI.

STAGE SIX

VALIDATION & USABILITY

"Did we build the right device?" – for the right users, in the right environment.

STAGE VI · VALIDATION & USABILITY

A device can pass verification and still fail in the room.

Validation asks whether the device works for its *intended users*, in its *intended environment*, for its *intended use*. The three nouns in that sentence are why the Stage 1 documents had to be written so carefully.

Usability engineering, under IEC 62366-1, is the dominant validation activity for most devices. Formative studies, run during development, surface use errors and inform design changes. Summative studies, run on the final design, demonstrate that the residual risks of use are acceptable. The two are not interchangeable: a summative study cannot be retroactively assembled from formative data.

Labels, instructions for use, quick-start guides, warnings, training materials and reprocessing instructions are part of the device for validation purposes. They are validated together. A device that performs perfectly with a hidden expert user but whose label causes a clinician to misuse it has failed validation. The label is a risk control, not a marketing surface.

41	Formative evaluation protocol & records	• REQUIRED
42	Summative evaluation protocol & records – *the headline usability deliverable*	• REQUIRED
43	Usability engineering file – *assembled, per IEC 62366-1*	• REQUIRED
44	Validation protocols & records – *clinical / simulated use*	• REQUIRED
45	Instructions for use, labels & warnings – *validated artefacts*	• REQUIRED
46	Clinical evaluation report – *per MDR Annex XIV*	○ IF EU PATHWAY

WHERE TEAMS STUMBLE

Summative usability is treated as a late-stage task and scheduled after design freeze. The study surfaces a use error that requires a design change. The change requires a new summative – except now the timeline does not allow one, and the project ships with a known risk that the team hoped would be acceptable.

Labels and IFU are written by marketing or by an engineer over a weekend, and never run through the usability process. The first time a real user sees them is in the summative – at which point the warnings, icons and step ordering all need to change.

HOW WE PARTNER AT THIS STAGE

Human factors sits inside our design team, not bolted on afterwards. Formative studies inform industrial design and IFU work as they happen; summative validation runs against a frozen design we already trust. Labels, IFU and training materials are designed alongside the device, not assembled at the end.

TALK TO US ABOUT USABILITY & VALIDATION →

VII.

STAGE SEVEN

TRANSFER & RELEASE

A working prototype is not a manufacturable device. The last documents prove it can be made repeatedly.

STAGE VII · MANUFACTURING TRANSFER & RELEASE

From a unit that works to a unit that can be repeated.

Design transfer is the moment a project stops belonging to engineering and starts belonging to operations. The documents that govern this transition are the ones that decide whether the next thousand units will be the same as the one verified, validated and signed.

Process validation — IQ, OQ, PQ — is the formal mechanism. Installation Qualification confirms that equipment was installed correctly; Operational Qualification confirms it runs within specification; Performance Qualification confirms it produces conforming product over time. Each step has a protocol, a record, and a report, and each is linked to the device requirements being upheld.

Around process validation sits the rest of the manufacturing file: a device master record describing what is built and how, supplier qualification records describing where the parts come from, incoming and in-process inspection procedures, the device history record describing what was built and when, and the final release records — GSPR checklist, design release, declaration of conformity — that close the design history file.

47	Manufacturing flowchart — *the process, named*	• REQUIRED
48	Process specification & URS — *what the process must do*	• REQUIRED
49	Master validation plan — *maintained from Stage 1*	• REQUIRED
50	Process validation plans & reports — *IQ / OQ / PQ*	• REQUIRED
51	In-process control specifications	• REQUIRED
52	Receiving & final inspection procedures	• REQUIRED
53	Approved supplier list & qualification records	• REQUIRED
54	Device master record — *recipe for production*	• REQUIRED
55	Device history record — *evidence of each unit built*	• REQUIRED
56	Design transfer checklist — *closing the engineering handover*	• REQUIRED
57	GSPR / Essential Principles checklist	• REQUIRED
58	Design release record — *authority to manufacture*	• REQUIRED
59	Declaration of conformity / submission package	• REQUIRED
60	Post-market surveillance plan — *and PMCF, if EU*	• REQUIRED

WHERE TEAMS STUMBLE

Process validation is started after the design is frozen, but discovers that the process cannot consistently hit a tolerance the design assumed. The fix is either a tolerance change (which re-opens verification) or a process change (which re-opens validation). Both are slower than involving manufacturing earlier.

Supplier qualification is informal. The contract manufacturer's audit was done; their critical sub-suppliers were not. Six months after release, an unannounced sub-supplier change creates a non-conformance the team has no way to investigate.

HOW WE PARTNER AT THIS STAGE

Manufacturing is part of what we do, not a hand-off to a third party at the most fragile point in the project. We transfer the design into our own production capability — process validation, supplier qualification, DMR and DHR set-up, final release — and produce the submission pack in the form the notified body or FDA actually wants to see.

TALK TO US ABOUT TRANSFER & MANUFACTURE →

10

SELF-ASSESSMENT

A TEN-QUESTION GAP CHECK

Where can you answer "yes" – clearly, in a sentence – without checking first?

§ 10 A TEN-QUESTION GAP CHECK

Ten questions you should be able to answer without looking.

If you find yourself hesitating on more than three of these, the documentation pathway probably has gaps that will be cheaper to address now than later. Tick the ones you are confident about.

The check

Each question is a yes/no. Tick if you can answer "yes" with evidence – not a verbal assurance from someone on the team. Score appears below as you tick.

- [ ] Can the team produce a current intended use statement that matches the device being built – and is identical across the regulatory file, clinical materials and investor deck?
- [ ] Does every user need link to one or more design inputs, and every design input to a planned verification activity?
- [ ] Are design inputs phrased as measurable, testable requirements – not aspirational statements?
- [ ] Is the risk file under live revision, with hazards traceable to the design outputs, verification activities and labelling that control them?
- [ ] Are drawings, BOMs and software builds under document and configuration control, with controlled revisions named in the verification records?
- [ ] Can you identify, today, the exact configuration of the units that went into biological evaluation, electrical safety and shelf-life testing?
- [ ] Has a formative usability study run on the user interface, IFU and labelling that will appear in summative testing?
- [ ] Are IFU, labels, warnings and training materials being developed inside the design process – not bolted on at the end?
- [ ] Is the manufacturing partner running on the same drawings, specifications and process documents that the design team approved?
- [ ] Could you, today, produce a one-page traceability summary from any user need to the test report that verifies it?

Confident answers: *0* / 10 Tick what you can answer with evidence. DISCUSS GAPS WITH US →

11

HOW WE WORK

ENGAGEMENTS

We tend to be useful at one of three moments — at the start, at a stuck point, or at the end.

§ 11 WHERE INTELLIDESIGN COMES IN

One team, from the first sketch to a manufactured device.

IntelliDesign is a medical-grade electronics design and manufacture house. We take products from *concept*, through development and regulatory approval, into *repeatable production* — inside one team, on one design history file, certified to ISO 13485 and AS9100D, without the discontinuities that ordinarily appear at every hand-off.

Most projects come to us at one of three moments — at the very start, when a founding team has a clinical insight and needs a partner who can deliver a real device; mid-flight, when an existing project has stalled and the documentation pathway has drifted from the design; or close to release, when the team has built something that works and now needs to prove it, transfer it, and make it repeatedly. In all three cases the work runs on the same three pillars: **design**, **engineer**, **manufacture**.

What we do, end-to-end

01 **Concept & feasibility**

Pre-study, intended use, technology selection, regulatory pathway. The first ninety days, where the decisions that shape every later document are quietly made.

02 **Industrial design & human factors**

Form, ergonomics, use environment, task analysis, formative studies. The design work that lets engineering follow a clear, validated specification.

03 **Mechanical engineering**

CAD, drawings, tolerance analysis, materials selection, DFMA, prototyping. Outputs under document control from the first revision.

04 **Electronics & embedded software**

Schematics, PCB layout, firmware, application software, connectivity. Developed under IEC 62304 from the first commit, not retrofitted later.

05 **Regulatory & quality**

ISO 13485 QMS, risk management (ISO 14971), usability engineering (IEC 62366), technical files, submission support for the TGA, FDA and notified bodies.

06 **Verification & validation**

Protocol authoring, in-house and third-party lab management, summative usability, V&V summary reports that hold up under audit.

07 **Manufacture & design transfer**

Transfer into our own production capability — process validation, supplier qualification, DMR, DHR, release. Scaled, repeatable build from the same team that designed the device.

08 **Sustaining engineering & post-market**

Change control, complaint handling, post-market surveillance, design updates and next-generation work. The job that begins when the first device ships.

How a first conversation tends to go

Thirty minutes, one call, no presentation. Bring the device, the stage you are in, and one or two things keeping you awake. We will tell you what we think the next three months should look like, and whether bringing us in makes sense from where you are.

If it does, we scope a short diagnostic in writing. If it does not, we will say so — and usually point you to someone who is the better fit.

We have never met a project that could not be moved forward by the next correctly-built component, or the next correctly-written document. The trick is knowing which one.

If any part of this guide felt familiar, the conversation is probably worth having.

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