

Pre-Audit Checklist		
	Requirement	What the Notified Body expects to see
1	QMS documentation complete	All SOPs, templates and the Quality Manual in place, signed and approved. The documents need to be adapted to your company!
2	Job descriptions written & signed	All relevant roles must have a documented and signed job description.
3	Organisational chart available	PRRC (for MDR) and Management Representative clearly identified.
4	Training records complete	Evidence that every employee has been trained according to their job description – documented and signed off.
5	First internal audit completed	Conducted, documented, and any findings addressed. Engaging an independent consultant for this step will give you valuable feedback to your audit readiness.
6	First management review completed	Meeting held, minutes recorded, inputs and outputs documented.
7	Quality objectives defined	Measurable objectives documented and communicated to the team.
8	Supplier qualification complete	Critical suppliers qualified and listed in an Approved Supplier List.
9	Working QMS – min. 6 months	Some Notified Bodies accept 4 months. The system must be demonstrably active, not just on paper. And no – it is not sufficient if just the quality manager knows the SOPs.
10	EUDAMED actor registration	Actor registration in EUDAMED must be completed and a number assigned so that the Notified Body can actually start the review process (they need to log the number). Note: If your company is based in Switzerland, you will also have to start the Swissdamed registration in parallel.