EUDAMED Actor Registration (SRN) — One■page process

Purpose: help you prepare a submission-ready actor dossier and understand EU vs non■EU paths.

EU/EEA actor (EU establishment)

1. Create EU Login / access prerequisites
2. Submit Actor Registration request in EUDAMED
3. Competent Authority assesses & validates
4. SRN issued (store evidence & keep details up to date)

Non■EU manufacturer

1. Appoint an EU Authorised Representative (AR)
2. AR verifies the registration request (pre■check)
3. Competent Authority assesses & validates
4. SRN issued (keep mandate + evidence pack ready)

What we deliver (ops-focused, not legal representation)

- Actor data checklist + gap report
- Submission-ready actor dossier (structured fields, identifiers, evidence pack)
- Pre-validation against completeness & consistency (reduce rejects/rework)
- Change log template for ongoing updates

Notes

- SRN is issued by the relevant Competent Authority, not by service providers.
- For non■EU manufacturers, AR verification is a typical required step.
- Keep roles clear: we prepare the data pipeline & evidence pack; your AR/CA performs formal verification/issuance.