

MEDICAL DEVICES · AKD / AKL

Medical Device Registration (Ministry of Health)

Registration of locally made (AKD) and imported (AKL) medical devices with the Ministry of Health, including preparing the distribution certificate (CDAKB).

What we handle

Risk Classification Determine the device risk class and its requirements.	Distributor & CDAKB Distributor licence and Good Distribution Practice readiness.
Technical Dossier Specs, IFU, test results, ISO 13485 and Certificate of Free Sale.	Registration Number Filing and evaluation responses until approval.

Documents required

- ☐ NIB and medical device distributor licence
- ☐ CDAKB certificate
- ☐ Letter of Authorisation from the manufacturer
- ☐ ISO 13485 and Certificate of Free Sale (imports)
- ☐ Technical specs, IFU and test results
- ☐ Indonesian-language label design

General process

1	Product Classification Risk class and registration route.	1-3 days
2	Distributor Readiness Distributor licence and CDAKB certificate.	2-6 weeks
3	Dossier Preparation Technical and manufacturer legal documents.	2-3 weeks

4	Ministry Evaluation Evaluation and corrections if requested.	4–8 weeks
5	Registration Issued AKD/AKL number on the label.	Upon approval

Timelines are indicative and may vary by product, scheme and authority policy. Contact us for an accurate assessment.

Free consultation

Send us your product specifications and we'll prepare a quote within one business day.

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