CDSCO Regulatory Readiness Checklist

Pre-submission checks for medical device and IVD applications in India

Medical Devices Rules, 2017 | Central and State Licensing Authority pathways

Run these checks before submitting any CDSCO medical device or IVD application.

Product

- [ ] Intended purpose clearly defined
- [ ] Indications defined
- [ ] Users identified
- [ ] Patient populations defined
- [ ] Medical claims documented
- [ ] All variants identified

Classification

- [ ] Medical device status confirmed
- [ ] Risk class established
- [ ] Latest CDSCO classification list checked
- [ ] Applicable classification rule documented
- [ ] Predicate status assessed

Regulatory pathway

- [ ] Import or manufacture determined
- [ ] CLA or SLA identified
- [ ] Standard or novel device pathway confirmed
- [ ] IVD pathway assessed where applicable
- [ ] Software pathway assessed where applicable
- [ ] Clinical investigation requirement determined
- [ ] Clinical performance evaluation requirement determined

Evidence

- [ ] Risk management
- [ ] Verification
- [ ] Validation
- [ ] Performance testing
- [ ] Clinical evidence
- [ ] Analytical performance where applicable
- [ ] Clinical performance where applicable
- [ ] International evidence mapped
- [ ] Literature

Technical documentation

- [ ] Device Master File
- [ ] Plant / Site Master File
- [ ] Manufacturing information
- [ ] Quality documentation
- [ ] Risk documentation
- [ ] Test reports
- [ ] Clinical and performance evidence
- [ ] Standards
- [ ] Declaration of Conformity

Labeling

- [ ] Label
- [ ] IFU
- [ ] Warnings
- [ ] Precautions
- [ ] Contraindications
- [ ] Storage conditions
- [ ] Manufacturer information
- [ ] Intended-use consistency across the file

Regulatory submission

- [ ] Correct application form
- [ ] Correct authority
- [ ] Fees
- [ ] Authorized agent documentation where applicable
- [ ] Power of Attorney where applicable
- [ ] Regulatory certificates
- [ ] Free Sale / Marketing Authorization documentation where applicable
- [ ] All required annexures

Post-market

- [ ] Complaint handling
- [ ] Adverse event reporting
- [ ] Post-market surveillance
- [ ] FSCA procedure
- [ ] Change control
- [ ] Software lifecycle management where applicable

Form quick reference

Activity	Application	License
Import (all classes)	**MD-14**	**MD-15**
Manufacture Class A/B	**MD-3**	**MD-5**
Manufacture Class C/D	**MD-7**	**MD-9**
Clinical investigation	**MD-22**	**MD-23**
No-predicate device	**MD-26**	**MD-27**
New IVD performance evaluation	**MD-24**	**MD-25**
New IVD import / manufacture	**MD-28**	**MD-29**

Notes