Revised Classification Table – Checklist

- Identify your device's updated CDSCO risk class (A, B, C, or D)
- Check if your device has been removed from the old "General Hospital" or legacy classification category
- Identify the new CDSCO category under which your devicecan be listed
- Compare the revised classification with the previous one to understand regulatory impact
- Determine whether your device now falls under a higher or lower risk class and assess regulatory consequences
- Review new licensing requirements based on the updated class
- Confirm if import or manufacturing licenses require amendment or reissuance
- Determine whether inspection, audit, or certification by a Notified Body or CDSCO-approved authority is now required
- Determine if new testing or performance data is required
- Review any additional documentation requirements introduced by the new class
- Update your technical file or device master file accordingly
- Ensure your QMS aligns with the class-specific CDSCO requirements
- Revise product labeling, Instructions for Use, and declarations if classification affects claims, indications, or intended use
- Confirm timelines for compliance based on CDSCO notifications
- Prepare to submit revised information through the CDSCO online portal
- Inform distributors or partners of any changes that affect supply or sale
- Maintain internal records showing compliance with the revised CDSCO classification