China Medical Device Regulatory Consulting

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Testing Procedure

Technical document gathering according to the check list

- Prepare the required documents checklist
- Technical documents gathering and reviewing

Draft the product standard (technical requirement report)

- Draft the product standard according to the industrial standard in China

Draft the Chinese instructions and label

- Draft the Chinese instructions and label for the testing unit
- Reviewed by the applicant and laboratory

Confirm the testing requirements with the qualified laboratory

- Confirm the testing laboratory
- Confirm the testing requirements with the sample quantity
- Apply for test exemption for some specific items

Submit the application form and sample to the laboratory

- Prepare the application form and reviewed it by the applicant and laboratory
- Deliver the sample with application materials to the qualified laboratory

Follow up the testing and supplement doc. If required

- Follow up the testing and coordinate with the laboratory
- Technical specification modification and document supplementation

Finalize the product standard and testing report

- Finalize the product standard after reviewed by the applicant and laboratory
- Finalize the testing report

Acquire the final testing report

- Acquire the final testing reports (two original versions in Chinese)
- Deliver one version to the applicant