



The Work Dictates for Pre-assessment of Medical Device Product Standards

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Test Report No. :

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1. The integrity and applicability of the performance index in product standards;
check the operability and repeatability of the inspection methods, and make sure
it can match the inspection requirement.
2. All the national standards and industrial standards used in the inspection must be
integrated, applicable and appropriate.
3. The testing content that refers to <Chinese Pharmacopoeia> must be integrated,
applicable and appropriate.
4. Other issues to be explained
5. Comprehensive assessment :
 - ☐There is no supplementations or suggestions for product standards.
 - ☐Following aspects shall be modified for product standards:
Performance index:
Applicability for national standard and professional standard:
Contents cited from <Chinese Pharmacopoeia>:

Date: m/d/y