



FAQ standards recognition in Korea

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Question 1 – How to search for local standards?

Answer – Go to KSSN (Korean Standard Service network) webstore:

http://kssn.net/English/WebStore/C_WebStore_list.asp

Select KS when searching (not IEC or ISO). Use the international standard code such as “60601-1” or “10993-1”. The result will show the status of the local standard

Question 2 – How to search for local deviations?

Answer – Based on search described in Question 1 there are 3 cases for the status of the standard:

Identical(IDT), Modified(MOD), Not Equivalent(NEQ)

If modified you’ll have to look for deviations in the standard.

If not equivalent, there will be another standard addressing the requirements.

Question 3 – How test reports for active products are recognized?

Answer – To be recognized, the tests reports have to be issued by a recognized IECCE member. Local deviations have to be applied. For class 3 and 4 products it is asked generally that all tests are performed under local power conditions (220Vac @ 60Hz)

Question 4 – How reports for non-active products are recognized?

Answer – Test reports have to be issued by a Good Laboratory Practice recognized lab. GLP lab definition is as per FDA CFR part 58.

Question 5 – How quality system standards are recognized?

Answer – Quality system standard like ISO 13485 is entirely included in the medical act. Therefore it can be said that there is no deviation from this



point of view. However the way a KGMP inspection is carried differs from an ISO 13485 audit and the reviewed documents may be different

Question 6 – When should I consider testing in Korea?

Answer – Testing in Korea should be considered in the following cases:

- Korea is a major market for you
- There is limited budget to afford a CB report
- The product is class 3 or 4

Question 7 – What are the accredited labs in Korea?

Answer – There are 14 accredited labs in Korea. The main and generalist ones are: KTR, KTC, KCL, KTRI. The rest are university based and in most case specialized in products like dental

Question 8 – What is the cost of testing in Korea?

Answer – The cost vary of course but it is quite affordable. For instance for an active product, EMC, electrical safety and performance (particular standards) can be tested for around 6000-7000 USD.

