

Notice about abroad medical device labeling and package mark

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To each SFDA (SDA) in all the provinces, autonomous regions, municipalities:

Recently, some local SFDA(SDA) meet questions related to abroad medical device original labeling and package mark have such words "Made in XX"(Country) which are different from the manufacture address on registration table attached to SFDA certificate. It is regarding to the administration rules of PRC and international trade rules.

1. According to *<Medical device registration management rules>* (SFDA Direction No.16) clause 48 and *<Medical device User's manual, Labeling and package mark management rules>* (SFDA Direction No. 10) clause 5, clause 6 and clause 15, the user's manual, labeling and package mark of abroad medical device shall use Simple Chinese, and it is allowed to use other language for supplementary.
2. Follow WTO relative rules, abroad medical device manufacture should mark the original manufacture country (e.g. Made in XX) on some parts of imported medical device labeling and package, it may be different from the content of "manufacture address" on Chinese labeling and package mark. This is accepted by China SFDA.

China SFDA
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