

Identifying NBs and AOs

EU NBs

For EU Notified Bodies, NBs, start with the EU's official list. Determine the directives you are interested in from the list at <http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main>

Click on the link and you will get a list of Notified Bodies to that directive. Notice that it is by country, and the US is not listed. Many of these Notified Bodies have a US affiliate.

A word of caution however. Many Notified Bodies to the current directives (MDD, IVDD, and AIMD) will not qualify for the new regulations (MDR and IVDR), so be sure to learn their plans. The process to become an NB for the regulations starts near the end of 2017. The first companies should have NB status by about April 2018.

AOs

Another consideration is Canada. If you want to sell in Canada, you will need an MDSAP certificate to get a license from Health Canada. The list of Auditing Organizations, AOs, is at <https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429978.pdf>. This list changes over time, as companies go through the process.

Some companies plan to be an NB to the directives, an NB to the regulations, and an AO for MDSAP. These companies will have capacity problems during the transitions, so be sure to find out how they are scheduling audits.