10 important tips

for testing & certification of electrical medical devices

1. Start on time

Perhaps it's obvious, but start well in advance to find an organization that will support you with the testing, inspection and certification your electrical medical device. Ideally you should get in touch at least six months in advance. That should leave you with enough time to discuss the possibilities and meet your time-to-market deadlines.

2. Collect relevant information

Curious to learn more about the entire testing and certification process? Gather as much information as possible in advance! At DEKRA we offer an online face-to-face session with a DEKRA expert, who will give you all the information you need for free. They will be more than happy to tell you more about what this process would look like for your specific situation.

3. Identify your export market

In which countries would you like to sell your electrical medical devices? Identify your export market before launching the testing and certification process. Including this step directly in the certification of your products (for a small additional fee), could ultimately save you substantial costs.

4. Consider future developments

Good preparation is half the battle. Before you start the testing and certification process, it's important to consider future functionality, target markets and sufficient availability of components. Changes to your product's design will have consequences for its certification. Identifying this well in advance lets you avoid delays in your go-to-market strategy.

5. Prevent non-conformities

A non-conformity often results in time being lost and unnecessary additional costs. You can already do a lot yourself to avoid nonconformities and speed up the certification process. Here's a brief checklist of some of the possibilities:

- ✓ Are there components that come into contact with the patient?
- ✓ Are the components made of materials with the right bio-compatibility?
- ✓ Are all the critical components certified? For example:

- PCB
- Power supply
- Plastics
- Adhesive tape
- Connectors
- Switches
- Fuses
- Capacitors
- Batteries
- Fuse-holders
- Transformers
- Enclosure
- Resistors
- Lasers
- Etc.

Extra tip: It is also possible to have an early scan of your product based on a pre-compliance check by one of our engineers.

6. Deliver your sample on time

Deliver the test sample to the test lab on time. This will prevent delays, resulting in longer lead times and the possibility of having to postpone your product launch.

7. Involve an experienced engineer

For complex products, engage an experienced engineer to install the product in the test lab on site. Is peripheral equipment needed for the test setup? If so, make sure it also arrives on time at the desired test location.

8. Identify the right standard versions and regulations

When a standard changes it it affects the testing and certification process. Make sure the standard versions included in the tender are the correct ones. Our DEKRA experts will be happy to help you identify the correct standards and versions.

9. Involve an external expert

Get the test lab's expert to look over your shoulder during the development process. Consider an engineering review and/or document check that serves as a baseline measurement. DEKRA has developed a online 'guidance session' for this. It gives you the opportunity to be in direct contact with a DEKRA expert and get the answers to all of your technical and/or standard related questions. Do everything you can to increase your First Time Right success!

10. And so to work!

Ready to have your electrical medical equipment tested and certified? Our DEKRA experts will be happy to help you ensure that the entire process runs quickly and smoothly.
Request a free information session now.

Contact

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