metecon
the service company

TECHNISCHE DOKUMENTATION

TECHNICAL DOCUMENTATION

Safety over the entire product life cycle

Technical documentation is the evidence that a product corresponds to the regulatory requirements, needed to be certified by your appointed body. But it doesn't end there. Technical documentation must remain up-to-date over the entire life cycle of your product in order to seamlessly validate the safety of your product. Is your workload set to increase with the new MDR?
We're here for you.

Your benefits

- For the continuous market success of your product: Product portfolio streamlining and product strategy for the changeover from the MDD (Medical Devices Directive) to the MDR (Medical Devices Regulation) by 25 May 2020 and beyond.
- Ready to sign documents for submission (international) or product certification (EU) with your templates.
- With our extensive experience we can achieve your objectives quickly and efficiently
- You gain valuable expertise for your next development projects.

FROM MDD TO MDR: WHAT NEEDS TO BE DONE?

Some think three years is a long time, while others are confounded and look at the big mountain of work. It's actually a matter of waiting to see how the notified bodies interpret the changes, so as to be able to derive a detailed course of action. Nevertheless: There's a lot to be accomplished. If you're to have all product files ready in line with the MDR within the short transition period, a certain amount of preliminary work needs to be done: Firstly, as a manufacturer of many different products, an effective strategy must be developed quickly to be able to bundle these according to product groups. Secondly – irrespective of the number of products – it's now important to update all existing product files according to the Medical Devices Directive because this is essential for raising them to MDR level by 2020.

OUR SERVICES

Compiling and maintaining technical documentation

· Creating the content of technical documentation (EU and international) – in compliance with standards and the law,
· Checking technical documentation for medical devices already on the market against current regulatory requirements,
· Maintaining and updating technical documentation over the product life cycle,
· Communication with notified bodies, authorities and test laboratories.

Format of the technical documentation

· Advice concerning the structure and content of technical documentation,
· Drawing up the submission documents in accordance with the requirements of the destination country.

Whatever your subjects: We'll support you proactively. Don't hesitate to contact us!

"Successful product certification or submission documents complete conformity with the statutory regulations. Our know-how safeguards you in times of change."

Sonja Bruhn, Head of Technical Documentation

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