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6 good reasons for outsourcing in times of MDR

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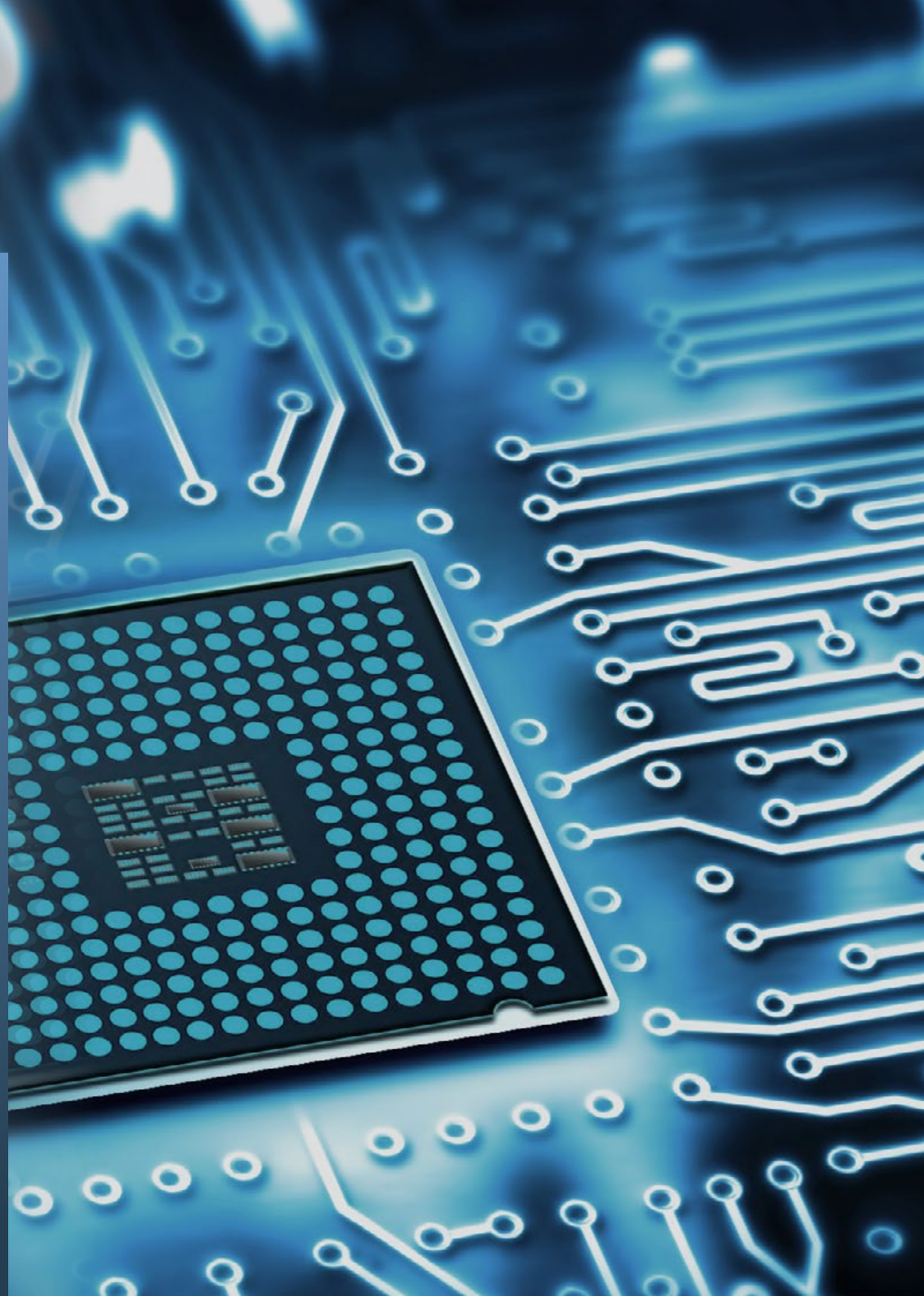

May 26, 2021: This date will be remembered fondly by some medical technology manufacturers and less fondly by others. The new European Medical Device Regulation (MDR) has been in force since this date, having been adopted by the European Parliament and the Council in May 2017. The MDR replaces the previously applicable Medical Device Directive (MDD) and regulates the necessary steps that a manufacturer must follow before a medical device can be placed on the market, as well as the obligations after it has been placed on the market.

Medical devices based on an MDD certificate that remains valid after May 26, 2021 may continue to be placed on the market until this certificate expires, but - depending on their class - until the end of 2028 at the latest. Nevertheless, many requirements of the MDR must be complied with without transitional periods. These include requirements for post-market surveillance (PMS), market surveillance, vigilance and the registration of economic operators and products. In addition, no further significant changes may be made to existing products. Manufacturers must therefore impose a “design freeze” on these products.

MDR as a major challenge for medical technology manufacturers

The introduction of the MDR is a major and immediate challenge for most medical device manufacturers. As if the implementation of the stricter regulations were not difficult enough, they come at a time when manufacturers are struggling to defend their competitive edge in a highly competitive market and are being forced into ever shorter innovation cycles. At the same time, margins are under pressure as customers and buying groups squeeze prices and additional requirements such as the MDR drive up costs. The question therefore inevitably arises as to how long-term corporate success and profitability can be ensured under these circumstances.

What will change for medtech manufacturers with the new MDR?

- Stricter regulations for the introduction of medical devices
- More stringent requirements for the quality and scope of clinical data and technical documentation
- Change in the classification of certain products / new classification rules
- Additional requirements for QM beyond the content of the contents of EN ISO 13485
- Introduction of UDI labeling for better traceability of products of products
- Greater responsibility of manufacturers for liability and Recording of complaints

How you can benefit from outsourcing right now

It is not surprising that more and more medical technology manufacturers are deciding to outsource and bring a professional OEM partner on board. How can the double-digit growth of the outsourcing market be explained and why can manufacturers benefit from this model, especially in times of MDR? We have compiled six good reasons for outsourcing for you.

1. You can focus on the essentials

The introduction of the MDR not only increases the requirements for the content of technical documentation. Numerous other critical processes are also affected: from manufacturing and post-market surveillance to risk management. Implementing an MDR strategy therefore requires a lot of time, expertise and resources. Depending on the size of your company, it may be difficult to drive forward the development of a new product and the establishment of an associated production infrastructure in parallel. An outsourcing partner is able to give you quick access to their expertise by doing what they do best: Develop products in compliance with MDR using highly specialized technologies and produce them ready for series production. Instead, focus on your true strengths and use the time as a distributor to implement and maintain a post-market surveillance system and conduct PMCF (Post-Market Clinical Follow-up) studies.

2. You simplify your supplier management

The explicit aim of the MDR to minimize the risks associated with medical devices for users and patients requires manufacturers to optimize supplier management. Close and contractually regulated cooperation between manufacturers and suppliers is necessary in order to be able to trace the entire life cycle of the products. It is important to describe the process of product identification and traceability along the entire supply chain within the manufacturer‘s process instructions. Use the outsourcing of the complete product life cycle as an opportunity to reduce the number of suppliers and thus meet the increased requirements of supplier management under MDR. Instead of having to deal with dozens of suppliers, you can focus on working with a single partner and save valuable resources and time.

3. You save costs

Medical technology manufacturers cite the higher resource requirements and the increase in costs as the biggest challenges associated with the introduction of the MDR. Around a third of manufacturers believe that this will cost them more than five percent of their annual turnover (Climedo EU-MDR Readiness Check 2020). If you outsource upcoming developments and production work to an outsourcing partner, you will not only save in the short term by not having to invest in machinery, staff development and training. You will also benefit in the long term because capital invested in innovation management, marketing and sales promises a faster and greater return on investment (ROI). Finally, you will also benefit from economies of scale by working with a larger and specialized OEM partner that can supply technology to multiple manufacturers.

4. You shorten the time-to-market

Many manufacturers are currently busy with internal homework due to the MDR. At the moment, only a few manufacturers already have a fully MDR-compliant quality management system. It would therefore not be surprising if many new product launches were to fall by the wayside, even though the products have already been fully developed. This is devastating, especially in times of a highly competitive market. Cooperation with an outsourcing partner who is able to take care of the entire design and development phase can significantly shorten the product launch timeline. In addition, a professional outsourcing partner has the know-how to achieve continuous productivity increases and eliminate idle times through the interaction of production technology and development. Last but not least, working with an OEM partner also eliminates the time-consuming process of setting up production facilities and processes.

5. you remain flexible

Especially in times of MDR, flexibility is crucial in order to be able to react to sudden and unforeseen changes in the market environment. By purchasing missing skills from an outsourcing partner, you eliminate the need to build up your own development and production expertise. This means that capacity bottlenecks can be eliminated elsewhere and peak loads can be compensated for. Many medical technology manufacturers are of the opinion that internal production can react more flexibly to changes - assuming that less additional work is required than if the changes have to be communicated to an external partner. In reality, an experienced outsourcing partner as a full solution provider has a much greater flexibility to change because it has a large infrastructure and operates under optimized processes. For the same reason, larger volumes of changes can be handled simultaneously, which benefits both smaller and larger production runs.

6. you are one step ahead of the competition

Are you struggling with an increasing number of me-too products? Have some of your products reached the end of their life cycle? Especially in times when a number of hurdles to MDR compliance need to be overcome, you should be looking to consolidate and expand your competitive advantage. While the competition is holding back new developments or taking existing products off the market, you can generate real added value through targeted innovations. An outsourcing partner can help you to bring high-quality products to market cost-effectively and quickly, while you continue to focus on your core competencies. Consider, for example, a peripheral expansion of your portfolio or the development of new application segments.

Even if the introduction of the MDR represents a major challenge for many medical technology manufacturers, it can be seen as an opportunity. Choose a partner with whom the chemistry is right and with whom you can imagine a long-term collaboration. Make sure that you can guarantee consistent quality management and thus the conformity and safety of your products. This is the best way to ensure that outsourcing is not only a cost-effective approach to accelerate market access, but also helps you achieve your goal of increased sales and improve people's quality of life through world-class products.

As a full solution provider, Brütsch Elektronik AG offers you offers you comprehensive expertise and professional project management from a single source. We take over the development and manufacture of your products and take care of the service. Contact us if you would like us to support you as an outsourcing partner in implementing the the new MDR.

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