GRÜNEWALD
GmbH

We will give you a smile

at the cost of MDR/FDA compliant product approval

Why should your competitors not participate in your MDR admission costs?

GRÜNEWALD
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The most (cost-) efficient solution for obtaining approval for your medical devices

Half a year before the EU Medical Products Regulation (MDR) comes into force on May 26, 2021, the German Medical Technology Association (BVMed) has called for better support for small and medium-sized enterprises (SMEs) in the MedTech sector. "93 percent of MedTech companies are SMEs. They are the backbone of this innovative industry and good patient care …" > more online

According to a survey published by BVMed, the EU-MDR will cost many manufacturers **> 5% of annual sales**.

This is where our **cost saving initiative** for MedTec manufacturers for **dental medicine & OMS surgery** comes in.

The grouping of comparable class 1 medical devices (product families) is a very effective approach to significantly reduce the effort and cost of MDR updates of your MDD product files.

This is true for any manufacturer, but especially if several manufacturers use the same MDR modules and for the (re-) certification of their products.

Would you share the cost of MDR updates of your existing products with your competitors?

Of course, the protection of confidential product information is guaranteed by us.

Specialists for the rapid development & approval of medical devices

For 20 years we have been consulting and supporting demanding and time-critical QM, MDD/MDR, IVDR, GMP and regulatory compliance projects. We master the complexity of regulatory, normative and GMP requirements and their interactions, e.g. via the risk-based approach. > more online

Our well-rehearsed team of engineers and scientists guarantees a high level of consulting competence and offers you additional helping hands for practical work. We would love to contribute our experience and best practices to your projects. We owe the trust of our notable customers due to the competence and commitment of our employees, as well as the exchange of knowledge and experience within the GRÜNEWALD team. Therefore, we work exclusively with our own employees and not with freelancers. > more online

Regulatory Compliance

The fastest secure way to market access and innovation & market leadership

> more online (DE)

MDR 2017/745, IVDR 2017/746, FDA 21 CFR 4, EMA, GAMP, Clinical Evaluation, MEDDEV

Quality Management

On course for growth with (audit) security and without unnecessary ballast.

> more online (DE)

ISO 13485, 21 CFR 820, MDSAP, PQS, EU-GMP, CSV, PMS/PMPF, CAPA

Risk Management

The risk-based approach to time and cost savings in development and production.

> more online (DE)

ISO 14971, ICH Q9, IEC 62366, Usability, Cybersecurity

Research & Development

Accompanying support of agile development from requirements engineering to TecFile testing.

> more online (DE)

GLP, IEC 60601, IEC 62304, IEC 82304, DU / UX, ISO 11073, ISO 15223-1, ISO 17664

GxP Production & logistics

Consulting & support for GMP conception, implementation & End2End process optimization.

> more online (DE)

GLP, EU-GMP, AMWHV, GAMP, cean room, ISO 14644, DQ, IQ, OQ, PV, CSV, relocation, risk-based ap-

Initiative for MedTec manufacturer dental medicine & OMS surgery

If you send us the list of your inventory products (without MDR certificate), we will use the Universal Medical Device Nomenclature System (UMDNS Version 1.1) for anonymous comparison with our article master data from "dental industry".

This leads to classification of families as well as how many product families **your product portfolio can be grouped together** for the MDR update, to which MDR class the products belong to, and how many manufacturers would share the costs for creating the document template for the respective product family.

Our MDR Compliance specialists / consultants create all required registration documents in a way that only a few manufacturer / product specific details need to be added to obtain a document ready for signature. In doing so, we ensure that all current regulatory and normative requirements are implemented in all documents and all data is up to date such as clinical evaluation or post-market data for instance.

Common modules of approval documents:

- Review and justification of classification I, Is, Ir, Im, IIa, IIb, III
- Define / check basic safety & performance requirements
- Evaluate clinical evaluation and post-market data
- Technical Documentation
- > more online

The costs of preparing / updating approval documentation for the respective product family are divided among all manufacturers using these documents for their product approvals. In the spirit of partnership and fairness towards competitors, all participants guarantee to use the documents exclusively internally and not to share them with other companies.

In this way you **minimize efforts and costs of MDR updates** of your existing products and maintain market access for the European market.

Please make sure to observe the MDR deadlines!

Regardless of the transitional period established by the third corrigendum of the MDR (**26 May 2021 according to Article 120(2)**), the validity of the approval of existing products (**26 May 2025 according to Article 120(4)**) and the special regulation for MDD approved products being assigned to another class according to the MDR such as e.g. reusable surgical instruments (**26 May 2024 according to Article 120(3)**), the date of 26 May 2021 continues to apply for the requirements for the designation of the **responsible person** (Article 15), the implementation of the requirements from **post-market surveillance** (Section 3) and **vigilance** (Section 2).

Saving OEM (Original Equipment Manufacturer) business

The EU Regulation 2017/745 on medical devices, the Medical Device Regulation (MDR) replaces the previous Marketing Authorization for Medical Devices (MDD) and **manufacturers**, **EU representatives**, **EU importers** and distributors must fulfill the requirements (Articles 10 - 14 of the MDR) by the end of the transition period in order to be continuously approved to the market of medical devices in the EU.

However, the MDR / IVDR era no longer recognizes **Original Equipment Manufacturer** (OEM) / Private Label Manufacturer (PLM). The "manufacturer" who has marketed the OEM's labelled product up to now needs to have full access to the product's technical documentation in the future.

We can also support your company to **maintain OEM business into the MDR/IVDR age** a neutral partner representing the interests of both parties as well as a trustee of the approval documentation.

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My business card
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