A Strong Partner for MDR Conformity

Development and Production of Medical Devices Are Changing Dramatically

The aim of the Medical Device Regulation is to further increase the safety of medical devices. With it, many products will be subject to a higher classification with considerably strengthened requirements in order to achieve CE conformity. Especially for small and medium-sized companies, it is a challenge to provide the required information for all components in the medical device.

Production in a cleanroom: in Stein am Rhein in Switzerland, Trelleborg can produce and pack in cleanrooms of class 7 and 8 according to ISO 14644–1 (class 10,000 and class 100,000 according to US FED 209D) © Trelleborg

The Medical Device Regulation EU 2017/745 (MDR) [1] entered into force on 25 May 2017 and will be fully applicable throughout Europe on May 25, 2020, following a three-year transition period. It replaces the previous Medical Device Directive and the Directive on Active Implantable Medical Devices. The scope initially covers all medical devices placed on the market from 25 May, 2020, as well as many products already on the market and is validated by CE conformity.

Though the new rules will ensure the smooth movement of goods within the EU's internal market, the fundamental aim of the new MDR is to increase safety and minimize the risk for patients.

MDR Raises the Bar

The requirements for a medical device are based on the device's classification into one of four classes (**Table 1**) according to the classification rules of Annex VIII of the MDR. The latter covers a wider scope than the previous regulations. The new classification criteria concern factors such as risk, contact duration and invasiveness of medical devices. For many product groups this will lead to higher requirements, as they are now classified in higher classes than before.

Particular attention must be paid to the selection of materials. For example, MDR regulates the occurrence of CMR substances (hazardous substances – carcinogenic, mutagenic and reprotoxic), endocrine disrupters, as well as nanomateri-

als and phthalates. In addition, manufacturers of products to which MDR applies must designate a qualified person to monitor compliance with the legislation and once on the market, the products are subject to continuous clinical monitoring. Comprehensive documentation obligations exist for the entire development of a device and the results of its continuous monitoring.

Especially for small and medium-sized companies, the collection and provision of the information necessary to meet MDR requirements may be difficult to manage, as is the provision of an appropriately qualified person to monitor compliance. It is therefore advisable to cooperate with competent partners to achieve CE conformity. These can help to identify the requirements for individual relevant components, depending on the application, and then to develop a strategy that considers all necessary requirements at component level from the beginning of the design process and material selection.

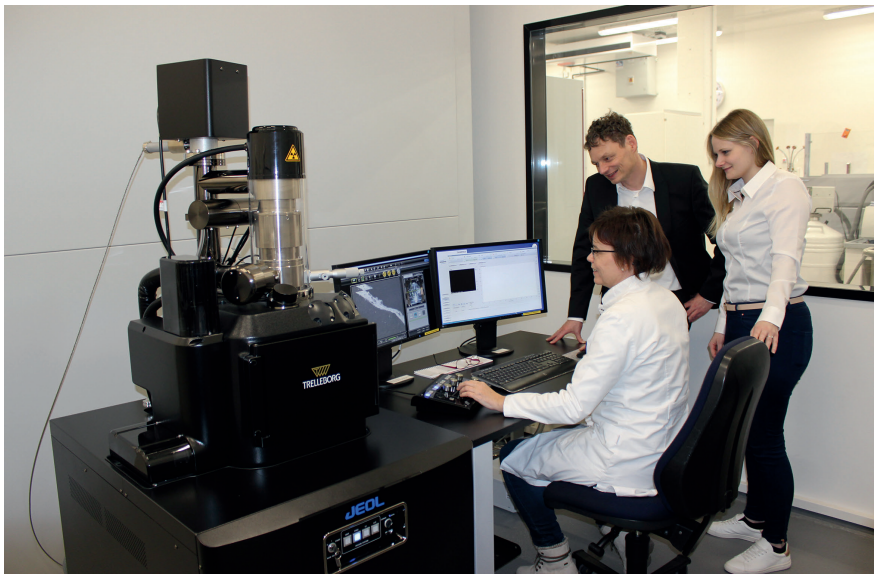

Fig. 1. Electron microscope in the laboratory: author Andreas Schmiedel with colleagues Florance Veronelli (right), Project Development Engineering, and Kerstin Holzinger, Materials Engineering, from Trelleborg Sealing Solutions © Trelleborg

For Approval with the Appropriate ISO Standards

As such a competent partner, Trelleborg Healthcare & Medical builds on MDR's strong relationship to ISO 13485 [2] and ISO 10993 [3] standards.

- ISO 13485 supports MDR's requirements for a quality management system for the design and manufacture of medical devices. It works with a risk-based approach, with the aim of considering the safety of the patient through all process steps, starting with the development of the medical device.
- ISO 10993 regulates the biological compatibility of medical devices. Accompanying the new MDR, a new revision of this standard was published in August 2018. It provides for the general avoidance of animal testing or a significant reduction in the number of animal tests required. Instead, the focus is on a much more precise physical/chemical characterization of the materials used.

In order to keep the risk in focus during design throughout the entire project, Trelleborg has decided to consistently handle all projects in the medical field according to ISO 13485. In addition, every area that is involved with medical devices is ISO 13485 certified. This enables Trelleborg to provide a continuous process landscape in accordance with a proven quality management system from the initial concept of a medical device to serial production and delivery to the customer.

Another important aspect regarding patient safety is the expert selection of materials. MDR tightens the previous »

	Class I	Class IIa	Class IIb	Class III
Criteria	■ No methodical risks ■ Low level of invasiveness ■ No or non-critical skin contact ■ Temporary application ≤ 60 minutes	■ Application risk ■ Moderate invasiveness ■ Short-term application in the body (in the eye, intestine, surgically created body orifices) ■ Short-term ≤ 30 days, uninterrupted or repeated use of the same product	■ Increased methodological risk ■ Systemic effects ■ Long-term applications ■ Non-invasive contraception ■ Long term ≥ 30 days, otherwise as with short term	■ High risk potential ■ Particularly high methodological risk ■ Long-term drug delivery ■ Ingredient of animal origin and in the body ■ Direct application to the heart, central circulatory system or central nervous system ■ Naturally invasive contraception
Examples	Wheelchairs, bandages	Dental crowns, contact lenses	Blood bags, condoms, X-ray machines	Artificial joints, absorbable sutures, heart valves

Table 1. Classification into medical device classes Source: Trelleborg

requirements for materials used in medical devices and regulates possible ingredients that are identified by chemical characterization. It is up to specialists to develop a suitable testing strategy to prove the basic suitability of a material. For this, the contents of ISO 10993 which regulates requirements for biocompatibility should also be considered.

In the future, manufacturers will require considerably more detailed analyses of their materials for certification. The testing of elastomers can be very complex, as they have different formulations. With its extensive range of test equipment, Trelleborg is able to carry out appropriate measurements. In addition, its many years of experience in sealing enables it to make recommendations on optimum materials and test methodologies. Trelleborg has scanning electron microscope with energy dispersive x ray spectroscopy (EDX), as well as state-of-the-art coupling techniques, such as gas chromatography-mass spectroscopy and many other pieces of standard test equipment.

Once the appropriate materials have been identified, Trelleborg supports its customers in designing a component for an application based on functional requirements, carrying out associated feasibility studies. Worst case considerations help to optimize the design in terms of risk minimization while design-for-manufacture ensures that the component can be manufactured cost-effectively on an industrial scale. Finally, the design is verified using mathematical methods, such as Finite Element Analysis (FEA) including tolerance estimates, and the entire process is extensively documented.

Quality Assurance and Customer-Specific Product Development

MDR attaches particular importance to the production of permanently high-quality products. The quality management system at Trelleborg focuses on minimizing risk for patients and the specifications for validation and verification are derived from the ISO 13485 standard, with production being automated as far as possible to avoid inconsistencies. Depending on the component manufactured, a 100% inspection can be carried out, preventing faulty parts from being incorporated into a finished medical product. If 100% inspection is not possible, the process can be validated. This ensures stability for the manufacturing process and the medical device. If required, production can be carried out in a cleanroom environment to achieve both particulate and microbiological cleanliness.

Successful cooperation with customers requires transparency in requirements and objectives and thorough coordination of all relevant parameters. Thanks to in-depth knowledge, individual solutions can be implemented in a comparatively short time potentially saving the customer money. It is important to carry out all steps in the optimum sequence in order to prevent possible fundamental planning errors, such as an unsuitable material, from being detected only at a later stage of development. In the worst-case scenario, this would mean that the part design would have to be revised and the entire planned production process would become obsolete. The development would have to start from scratch. ■

Company Profile

Trelleborg develops engineered polymer solutions that seal, damp and protect critical applications. The Group with its three business areas Industrial Solutions, Sealing Solutions and Wheel Systems, and a reporting segment, Businesses Under Development has annual sales of about SEK 37 billion (EUR 3.46 billion, USD 3.87 billion) in about 50 countries. The business area Healthcare & Medical supports pharmaceutical and medical device companies to develop engineered polymer solutions for demanding medical, biotech and pharmaceutical applications.

↘ www.tss.trelleborg.com/healthcare

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References & Digital Version

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