

MEDICAL DESIGN BRIEFS



**The New
MDR: Valve
Technology
Requirements**

**High-Speed Real-Time
Image Cytometry**

**Design Considerations
for qPCR Diagnostics**

MD&M West Show Preview



Medical devices in operating rooms are subject to MDR requirements. (Credit: Emerson)



Exploring **Valve Technology Requirements** Under the **New MDR**

Among the many standards and regulations affecting the medical device industry is the European Parliament (EU) 2017/745 standard, also known as the Medical Device Regulation (MDR).¹ First published in 2017, the MDR was on track to being fully implemented by May 2020. However, in light of the COVID-19 international health emergency, the European Commission and European Parliament postponed the deadline by one year to May 2021 (see the sidebar “CE Markings and MDR Changes”).

Although the pandemic has delayed the MDR’s validation date, it has not diminished the importance of this new regulation. This standard stipulates the

reclassification of many medical devices and requires stricter risk assessments. These changes place greater demands on medical device manufacturers — many of whom already face rising costs related to documentation, quality assurance, and quality management.

The good news is that there is an optimal approach to integrating fluid control and pneumatic components into medical equipment, enabling device manufacturers to meet the MDR’s newest requirements (see the sidebar, “What Are Medical Devices?”).

The Supplier-Buyer Relationship Under the MDR

Building on the requirements already in place, the MDR places higher demands

on medical device manufacturers in two key areas:

Quality assurance. The quality management system (QMS) standard EN ISO 13485:2016 is growing in importance, requiring audits by independent bodies.

Documentation. Manufacturers must record detailed technical descriptions, specifications, verifications, and validations for each medical device.

As a result of ISO 13485, manufacturers and suppliers are entering into quality agreements regarding change control, component traceability, record retention, audits, and the definition of a *critical supplier*. If one of these quality agreements is in place, the supplier must ensure that all technical documentation,

Valve Technology Requirements



Cleanroom manufacturing for medical device components ensures maximum purity. (Credit: Emerson)

processes, and infrastructure are in place to, for example, hand out material compliance certificates, successfully hold audits, and implement the proper information technology (IT) infrastructure to manage change control and component traceability. In addition, notified bodies have the right and duty to monitor and audit critical component suppliers. This is a new aspect under the MDR that medical device suppliers should be aware of.

So, what can suppliers do under the MDR to support medical device manufacturers in this new regulatory environment? There are three key aspects:

- First, suppliers should provide all relevant documentation, including clear technical specifications, drawings, bills of materials, material certifications (RoHS and REACH), ISO 9001 certificates, and quality agreements between the manufacturer and supplier. The supplier must also be knowledgeable about these various documents and be able to issue them in a short period of time.
- Second, suppliers should have various processes in place regarding change control, audits, and a stage gate process for new development projects.
- The third aspect involves infrastructure. An enterprise resource planning (ERP) system, for example, supports

component traceability from the sub-supplier to the customer. Suppliers should also have trained and knowledgeable experts on hand to tailor their products and services according to customer needs.

What Are Medical Devices?

The term *medical device* refers to products that have a medical purpose and are intended by the manufacturer to be used on humans. Examples include instruments, apparatuses, machines, implants, in vitro reagents, and materials used either alone or in combination with each other. In addition, these devices have a specific medical purpose and play a critical role in patient diagnosis, prevention, monitoring, treatment, or alleviation.

Considering their important functions, medical devices must achieve the highest levels of accuracy, reliability, and purity. These criteria apply to ready-to-use devices or machines, as well as to the components installed in them.

In short, under the new MDR, suppliers to medical device manufacturers must be able to deliver solutions consisting of both products and services — for example, documents, processes, and infrastructure.

Compact, Energy-Efficient Valve Technologies Under the MDR

Valves, which represent a core technology in medical equipment, play an important role in a variety of medical products such as surgical devices, ventilators, and dialysis machines. Current trends in valve technology as it pertains

to medical applications include miniaturization, energy efficiency, and weight reduction. For example, demand is growing for compact, economical valve units — particularly in battery-operated or mobile medical devices in the home care sector. In such applications, less-complex fluid control systems are critical. In order to optimize the flow path and contribute to higher instrument efficiency, fluidic components must meet ingenious application requirements. Such simpler designs also help to reduce manufacturing costs.

In addition, modern fluid control components and assemblies are designed to provide a high degree of reliability and availability, as well as long service life. These criteria are especially important when the valve must make direct contact with media supplied to or removed from a patient. Valve technologies tend to incorporate inert materials, feature low internal volumes to reduce cross contamination, and minimize power consumption for use in portable equipment. Cleanroom manufacturing capabilities additionally support the highest level of purity for components used in medical devices.

The MDR makes it more challenging to comply with industry regulations and approvals during the product development process. It also increases the

CE Markings and MDR Changes

Medical device regulations have major implications for patient care. One recent example is the previous European regulatory framework, which failed to prevent the use of substandard breast implants made of industrial silicone. The MDR introduces new medical device certification procedures to ensure that failings like these don't happen again.

Until May 2017, the European regulation for obtaining a CE marking — which indicates that a device meets health, safety, and environmental protection standards within the European Economic Area (EEA) — was the Medical Device Directive (EU), including 93/42/EEC and 90/385/EEC directives for medical devices and active implantable medical devices, respectively. In May 2017, however, the MDR replaced these regulations and instituted the following changes:

- Implementing stricter risk assessments of existing medical devices.
- Introducing a unique product key for all medical devices.
- Instituting more stringent regulatory monitoring.
- Requiring new certificates.
- Placing greater demands on manufacturers.

expectations placed on valve technologies and the respective manufacturers. Some examples of compact, highly efficient valve solutions used in medical devices include the following:

- **Miniature valves.** Miniature valves that make direct contact with media play an important role in applications like oxygen therapy, peritoneal dialysis, and patient monitoring. Many individual valves and pressure regulators are specifically designed to minimize leakage, reduce noise, and provide maximum mobility in these applications.
- **Engineered manifolds.** Fully tailored fluid control solutions according to



This valve manifold is an engineered solution for portable oxygen generators. (Credit: Emerson)

the medical device manufacturer's individual specification allow easier integration and reduce the assembly process. As an example, manufacturers of ventilators, which are critical life-supporting devices for many patients, use a sophisticated combination of proportional and miniature solenoid valves to regulate and adjust the gas mixture to meet patient requirements.

Learn More

To meet the technical requirements for medical devices, it's important to partner with a fluid control and pneumatics supplier with extensive industry experience. Companies that simply supply components may not understand how these components perform within the greater system. Collaborating with a partner that understands the complex demands of the medical market enables manufacturers to overcome challenges, develop further innovations, and meet the requirements of the MDR.

Reference

1. Regulation (EU) 2017/745, *The European Union Medical Device Regulation*, 26 May 2021, <https://eumdr.com>.

This article was written by Thomas Beck, Global Product Marketing Manager for Surgical and Therapy Equipment for Emerson's Analytical and Medical Segment, St. Louis, MO. Having worked for a manufacturer of Class IIb medical devices prior to joining Emerson, he is well versed in the impact of the MDR and the role of suppliers in this context. For more information, visit <http://info.hotims.com/82320-340>.



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