THE RIGHT SENSORS CAN HELP ACCELERATE REGULATORY APPROVALS

Honeywell

SENSOR DESIGN, CERTIFICATIONS AND EUROPE'S MEDICAL DEVICE MARKET

Sensors are critical to the efficacy of medical devices. They detect blockages within infusion pumps. They verify oxygen levels in ventilators. They can monitor micron-level fluctuations in body temperatures or breathing patterns or blood flows so medical devices of any kind can administer accurate care to any patient in need — in real time.

Today, there are more than two million medical technologies, products and services on the European market.[1] And there's still strong momentum for new devices. Because there are significant research and development investments in medical device innovation and because key manufacturing hubs across European Union (EU) member states are also fulfilling existing orders, high-performance sensors are in high demand. So is compliance with EU Medical Device Regulation (MDR) certification requirements.

The EU MDR is the strict regulatory framework that oversees medical device design, production and distribution. As the replacement for the Medical Devices Directive, the EU MDR's main goal is to help ensure devices are fit for use by strengthening liability, traceability and conformity to specifications across device classifications and critical components, including sensors.[2] This mandated scrutiny helps ensure patient safety. But constrained Notified Bodies, stringent documentation and post-market requirements result in significant certification delays — and place significant pressure on medical device manufacturers to get compliance right the first time. In 2026, European medical device approval can take up to two years or more in some cases.[3]

7 WAYS TO REDUCE MEDICAL DEVICE MANUFACTURING RISKS THROUGH SENSOR DESIGN

When Notified Bodies are overloaded and regulatory timelines are stretched, sensor design and selection can help compress approval paths and reduce avoidable review cycles that add even more time.

From a strategic sensing partner with proven application expertise across life sciences and regulated medical manufacturing, here are seven practical strategies that help original equipment manufacturers maintain product, certification and operational stability across the dynamic European medical manufacturing landscape:

1. **Choose sensing technologies validated for medical applications**
2. **Prioritise performance stability over time**
3. **Document regulatory and quality-system traceability**
4. **Have integration simplicity with ongoing and new projects**
5. **Build with lifecycle continuity in mind**
6. **Define design-in and acceptance criteria early at the sensor level**
7. **Work with a sensing partner that supports customisation**

THE EUROPEAN UNION IS THE WORLD'S SECOND LARGEST MEDICAL DEVICE MARKET AFTER THE UNITED STATES.[1]

1.

CHOOSE SENSING TECHNOLOGIES VALIDATED FOR MEDICAL APPLICATIONS

Technical expertise and a track record of performance matter, especially when repeatable reliability makes sensors and entire devices easier to certify.

Many of our sensors already have established performance data and documented qualification results to help support faster compliance with rigorous EU MDR requirements. Not only does this documented qualification help accelerate development timelines for new devices, but it also helps reduce redesign risk as contracts renew and overall demand for devices grows. From physical to chemical to optical sensors, we are proficient in how we select our components and materials — and in prototyping, development and testing.

Our upfront engineering rigor is designed to help reduce risk over the product lifecycle.

2.

PERFORMANCE STABILITY OVER TIME

Medical devices must function within validated limits from first use to last. Even with temperature changes, humidity fluctuations or routine cleanings, sensors are designed to maintain accuracy within validated limits throughout the device's intended use life, which can vary depending on application and operation conditions.

For patients, sensor design sits at the centre of therapy and essential outcomes. For manufacturers, sensors deeply affect risk controls and compatibility behaviour. Both groups require components that achieve compliance in factory settings and maintain it in the field long-term.

In addition to performance validated for medical device integration, Honeywell sensors protect stability over time with predictive calibration and fault alerts. These built-in technologies are designed to support continuous, precise device operation by reducing recalibration frequency and adding visibility into asset health. And with comprehensive insights at this component level, these technologies also help medical device manufacturers meet stringent data-reporting requirements throughout equipment lifespans.

3.

REGULATORY DOCUMENTATION AND QUALITY-SYSTEM TRACEABILITY

As manufacturers look to strengthen throughput and scale operations, necessitated by market increases in both volume and intensity of care, they need quality management systems that make it easy for Notified Bodies to validate sensing and device performance — the first time, or in the event of a recall.

We know how to work technically, down to every detail. And we can align component choices to documentation needs early through advisement and discipline knowledge. By tracking how our sensing components are manufactured, controlling evidence at the batch level and making our processes visible, we help reduce manufacturing risks like redesign, revalidation and the delays that come with both. What we document includes, but is not limited to: full specifications and tolerances, test methods and criteria, supplier quality certifications and change-notification procedures.

Honeywell precision sensing technologies are backed by reporting and tracking standards that meet the requirements of quality management systems and EU MDR regulations.

4.

INTEGRATION SIMPLICITY ACROSS PROJECTS

Unless medical device manufacturers are extremely specialised, making one device day in and day out for a niche application, they're often managing components, systems and technologies for multiple projects. As these pieces grow in amount, connectivity and intelligence, sensor integration simplicity can help OEMs work faster while reducing regulatory and revalidation risk.

Simple-to-integrate sensors from Honeywell help medical device manufacturers reduce risks across projects by:

- Shortening development times during feature upgrades, regional product variants and new product builds
- Flexing and adding to production capabilities as demand for miniature and portable devices grows, in particular
- Minimising regulatory burden and noncompliance during complex assemblies

5.

BUILD WITH LIFECYCLE CONTINUITY IN MIND

Patients and providers depend on long-term availability. Manufacturers need production continuity. This means medical devices must remain safe, compliant, available and supportable for years, even as quality regulations change — and especially as increasing demand strains component supply chains.

Because we know that disruptions in output are disruptions in care, we design long-life sensors with proven durability over years of continuous use. This helps reduce risks like expensive redesigns that can result from early end-of-life sensor components. We further support lifecycle continuity with a global manufacturing and distribution network designed to support consistent availability and delivery. And throughout the entire sensor lifecycle, we provide end-to-end support and technical expertise designed to support regulatory compliance efforts.

6.

DEFINE DESIGN-IN AND ACCEPTANCE CRITERIA EARLY AT THE SENSOR LEVEL

It's never too early to differentiate medical device manufacturing processes with upstream regulatory readiness, product quality guarantees and patient safety standards that help Notified Bodies streamline approvals. Sensor design inputs are the strongest place to start, setting measurable benchmarks for performance testing, biocompatibility where applicable and safe function throughout the life of the product.

At Honeywell, we help define sensor-level performance limits, environmental conditions and acceptance criteria before the start of a project to align with clinical claims and system requirements, which helps limit redesigns and EU MDR review questions.

We support manufacturers with medically proven sensors that have clearly defined performance insights, characterisation reports and application guidance. All help set realistic and regulatory-ready criteria up front.

7.

A SENSING PARTNER THAT SUPPORTS CUSTOMISATION

There's more to medical device manufacturing than producing higher output levels amid stringent regulations and approval delays. On a growing scale, devices require customisation in addition to greater volume. And customisation often starts at the sensor level.

Europe has more patients than ever, which means greater demand for devices that support longer care journeys and more treatment pathways. We help manufacturers offer patients and providers devices to their exact specs, enhancing outcomes and efficiency one customised sensor at a time. Our design-in support has helped manufacturers create more than 100,000 custom sensor configurations and variants to date.

Custom components, like force sensors within infusion pumps or airflow sensors in respiratory monitors, are complex, facing stricter clinical evidence requirements and increased scrutiny during evaluation and testing. We can help manufacturers meet application-specific requirements while reducing non-compliance risk.

7 WAYS TO REDUCE MEDICAL DEVICE MANUFACTURING RISKS

One strategic sensing partner to help you navigate all of them.

Certifications and supply chains. Customisation and consistent accuracy. We help medical device manufacturers bring advanced, reliable, connected care to operating rooms, hospital stays, pharmaceutical facilities and patient homes with extensively tested, precise sensors and deep expertise in the global and European regulatory landscape.

References

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2. Saint-Gobain, "EU MDR: What is it and why is it necessary?," October 7, 2023.
3. The European Association of Medical devices Notified Bodies, "What are the timelines for obtaining CE certification under the MDR or IVDR?," [Accessed March 23, 2026]

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THE FUTURE IS WHAT WE MAKE IT

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