



The Race to EU MDR Compliance Continues

Despite progress over the past year, medical device companies are still facing many questions, according to annual KPMG/RAPS survey.



With less than one year until May 2020, the Medical Device industry is still grappling

with achieving MDR compliance. Organizations now have a better understanding of the legislation, enabling them to assess their progress toward compliance with the new requirements. However, there are new questions—many of which remain challenging to answer despite the looming May 26, 2020 Date of Application. To help organizations get a pulse on where the industry stands and their progress relative to competitors, KPMG and RAPS surveyed more than 230 industry leaders again this year.



Although this paper presents complete survey results and guidance on next steps, some significant highlights from our research include:

- **Only 28% of respondents** with revenue of more than \$1 billion plan to declare full MDR compliance by May 2020.
- **57% of respondents** are still in the process of renewing their MDD certificates so they can leverage the much-needed transitional provisions (noted in Article 120 of the EU MDR).

This is not to say that industry is sitting idle. The amount of work and time required to fully remediate outweighs industry efforts thus far. It is of note that, in the 2019 KPMG/RAPS survey, respondents said the top two barriers to achieving MDR compliance were:

- 1 Lack of available timely guidance from the European Commission
- 2 Lack of internal resources

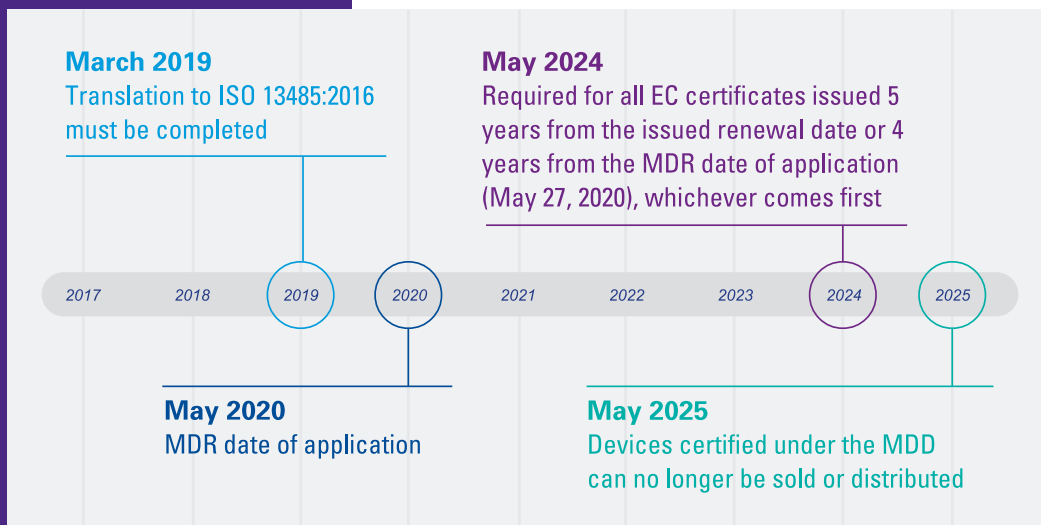
Given these two concerns, it is reasonable to assume that MDR will negatively impact not only the cost and continuity of medical devices, but also manufacturers' ability to innovate. Specifically:

36% of respondents estimate \$5 million+ in expenditures to achieve EU MDR compliance

More than 50% of respondents said they are planning on first/development product launches outside of Europe

66% of respondents have not started planning for the long-term organizational impacts of EU MDR, despite significant investment to date in remediation activities

EU MDR Timeline



Over-All Progress



The challenge

While the majority of respondents to the KPMG/RAPS survey have made significant process towards MDR compliance, only 27% believe they will be fully compliant by May 2020 without using the transitional provisions. In addition, more than half of respondents continue to cite a lack of guidance on standards and documentation as their most significant barrier to MDR compliance. Therefore, ensuring an end-to-end review of technical requirements in the remaining months before May 2020 is critical for all organizations planning to sell products in Europe post-May 2020.



What to do now

As the countdown continues, the time to perform a meaningful gap assessment against MDR requirements is fleeting. To ensure a seamless transition to an MDR future state, organizations should address the items in the following checklist between now and May 2020:

1. MDD Certification

- **Status:** 69% of respondents are in the process of renewing their MDD certificates (where possible/appropriate), which will allow them to avoid any misses during remediation and to use the transitional provisions to achieve compliance by May 2020.
- **Action:** Confirm that your organization is aligned on its MDD recertification strategy and remember that Class I devices are not covered by the transitional provisions.

2. Technical Files and Clinical / Medical Safety Documentation

- **Status:** When asked about the most significant documentation-related challenges their organizations face, 83% of respondents cited remediating and managing updates to technical files and Clinical Evaluation Reports (CERs).
- **Action:** As your organization manages its remediation process, now is the time to assemble a cross-functional team and verify:
 - Technical documentation is compliant with all 123 articles and 13 annexes of MDR.
 - All products have a MEDDEV 2.7.1 (Revision 4) compliant Clinical Evaluation Report.
 - All products have a process and template for a Post-Market Clinical Follow-Up Report.
 - In the absence of formal guidance from the EU Commission, a process and template for a Periodic Safety Update Report and Summary of Safety and Clinical Performance are developed.

3. Notified Body Strategy

- **Status:** More than 35% of respondents stated that the availability of notified bodies is a significant barrier to MDR compliance. This is a genuine concern because, as of September 2019, only four notified bodies have been designated, with no more than 10-12 designations expected by the close of 2019.
- **Action:** If you have yet to secure a notified body, you should make this an immediate priority. If you have secured a Notified Body:
 - Confirm their designation, as well as their strategy and schedule, and adapt your organization's MDR plan accordingly.
 - Early in the process, develop a schedule and strategy for reviews and audits.
 - Ensure your organization is communicating clearly with your notified body to avoid misunderstandings and misalignments in schedules and strategies for your compliance plan.

4. Device classification

- **Status:** MDR has required re-classification of many devices to a higher risk level.
- **Action:** Ensure that your product portfolio managers and the cross-functional team have assessed which, if any, products are impacted and implement an action plan for the applicable remediation of their technical documentation.

5. Quality Management System

- **Status:** 58% of respondents highlighted that, although they have made some progress towards the successful implementation of changes to their Quality Management Systems (QMS), they have yet to implement all the changes.
- **Action:** Ensure that your Quality organization has completed all required activities and updates before May 2020, including updating procedures and creating new ones, as necessary. Particular attention should be given to creating an internal audit checklist per the new requirements and conducting an internal audit before scheduling a Notified Body audit.



The long run

The rapidly approaching date of application means that Medical Device manufacturers will be balancing many priorities in the coming months. By

taking a systematic approach to the EU MDR regulation, organizational stress can be alleviated while ensuring compliance against MDR standards is maintained.

ISSUE 1

EUDAMED



The challenge

Nearly 48% of survey respondents have yet to develop a strategy for EUDAMED. As EUDAMED is one of the most significant changes specified by EU MDR, companies are still struggling to fully understand requirements and develop strategies for their implementation. For those organizations with a plan in place, 25% will continue with the manual process of data collection and submission to EUDAMED, 17% will leverage their existing IT infrastructure to manage master data requirements, and 7% will need to create new IT infrastructures.



What to do now

For companies that have yet to develop a strategy, it is critical to start with understanding the requirements and developing a roadmap for compliance. The European Commission's EUDAMED IT team has released draft documentation that expands on the functioning and requirements of EUDAMED modules. This documentation can serve as a guide for the development of a EUDAMED strategy, which should address:

- 1. CAMD guidance and subsequent delays:** EUDAMED is expected to go live in March 2020. Manufacturers have an 18-month grace period to register their devices in the database. The clock will either start in March 2020 (if EUDAMED is available), or in May 2020 (if EUDAMED is not available). In general, many manufacturers are choosing not to leverage the grace period, because the vigilance reporting requirements are effective from 2020. Device data will need to be registered in order to report vigilance MIR forms.
- 2. High-level EUDAMED requirements today:** The EUDAMED database comprises six modules, of which four will require action by the manufacturer and two will be managed by the Notified Bodies and Competent Authorities. The four modules that must be managed by the manufacturer are UDID – UDI & Device Registration, ACT – Registration of Economic Operators, CIPS – System on Clinical Investigations, and VGL – System on Vigilance and PMS. The two modules managed by Notified Bodies and Competent Authorities are Certificates & Notified Bodies, and Market Surveillance.
- 3. Action plan for EUDAMED readiness:** It is imperative to start EUDAMED planning and implementation now if it has not already begun. Companies can start by determining registration requirements for both legacy and MDR devices. They should also assess and assign Basic UDI-DI groupings to their devices. It is critical to understand the registration process for the different EUDAMED actors and obtain SRNs and roles/responsibilities for managing these actors. Manufacturers should also understand the additional reporting requirements for studies conducted in EU Member States, as well as more rigorous incident and complaint reporting expectations.



The long run

While many components of EUDAMED have been defined by the commission, manufacturers are still frustrated with a lack of clarity when it comes to requirements. Manufacturers are also awaiting technical specifications and interface gateway specifics to implement finalized system solutions. Even with fully developed EUDAMED requirements, it is difficult to foresee all the possible glitches and issues that might occur once EUDAMED is live. For long-term sustainability, it is crucial to ensure that robust change control processes are implemented now so that data can be managed and maintained on an ongoing basis. Also, companies need to clearly understand their current IT and resource bandwidth and adopt solutions that are integrated with streamlined business processes so they can become compliant today and adapt to future changes.



ISSUE 2

Acquiring notified bodies



The challenge

Last year's KPMG/RAPS survey identified "the bandwidth of notified bodies" as a significant concern for most respondents. Today, although 58 notified bodies are registered under MDD, fewer than five are certified for MDR, with only months to go until the final deadline. Further, although the commission is targeting a total of 20 certified bodies by the end of 2019, the rate of progress and lack of guidance are weakening organizations' confidence that they will be able to keep certain products on the market.



What to do now

While it is encouraging that 85% of survey respondents have identified and secured a notified body, it remains unclear whether they have done their due diligence to ensure their particular notified body will continue to meet their needs going forward. Further, the 15% of survey respondents that have not identified a notified body carry the greatest risk of not meeting MDR requirements. Both companies without a notified body and companies evaluating if their current notified body will continue to meet their needs should consider the following criteria before enlisting contract services:

- 1. Certification Offerings:** Not all notified bodies are certified for all directives. Only eight are currently certified for all three directives: MDD, AIMDD and IVDD. Companies should ensure that their notified body is certified for the directives with which they must comply. The full list of notified bodies and their respective directives can be found [here](#).
- 2. Experience:** It is critical to ensure that the notified body and its auditors have experience with an organization's device types. Since MDR is new for both notified bodies and companies, there will be a learning curve during which both may have to evolve together. Further, although auditors and companies may have different perspectives and interpretations of the requirements, they should be aligned on required device types and classes.
- 3. Markets Served:** Some notified bodies support markets outside of the EU. If the company has products in multiple markets, a notified body that can certify devices within those markets and has a local office presence would be advantageous.
- 4. MDR compliance plan:** If a notified body is not currently certified, ascertain whether there is a timeframe during which certification is expected. Although the MDR effective date is May 2020, the industry and commission are skeptical that there will be enough certified notified bodies to meet the demand. The commission is evaluating alternative plans for notified bodies to become MDR certified, including allowing other authorities to conduct assessments.

5. Reputation: Determine whether a notified body is a member of the Team NB, The European Association for Medical Devices of Notified Bodies. Team NB is an organization of notified bodies committed to quality and transparency among industry, health authorities, and themselves. Membership shows a commitment to “continuous improvement and development of products, allowing patients increased access to safe yet innovative devices.” Notified bodies are assessed annually by the responsible authority to determine if they still satisfy the requirements identified in MDR Annex VII, with a summary of the assessment provided publicly. Consider whether the notified body has continued to earn successful assessment reports.

6. Fit: Organizations should evaluate fees, expertise, resources, and expected timelines to determine which notified body is the best fit for the company. As with most contracting processes, evaluating two or more notified bodies is desirable.

7. Agreements: Once a notified body has been identified and/or if a company does decide to change its notified body, a detailed agreement should be established between the company, new notified body and, if applicable, the previous notified body to address: the dates certificates become invalid, transfer of documents, and the last date the previous notified body’s ID number can be used by the company, including on promotional materials.

For those companies that have already identified a notified body, many challenges are still present. The small number of MDR-certified bodies is insufficient to support the current demand from industry. Therefore, companies should consider the following tips:

- Clearly communicate with your notified body. Continuous communication of needs, expectations and wants will help minimize delays and misinterpretations.
- Schedule assessments and audits months in advance to give the notified body and company time to prepare.
- Manage timelines through project managers to mitigate stock outs, shortages and missed product launch timelines.



The long run

Going forward, companies and notified bodies will need to work collaboratively to meet EU MDR requirements. Notified bodies are reporting that audits from the competent authorities are more detailed than previous audits so companies should be prepared for more scrutiny. Specifically, quality system, technical documentation, demonstration of clinical evidence, post-market safety reporting, and more are being requested and reviewed before authorities come onsite. Further, authorities are prepared with observations and detailed questions.

Notified bodies and companies should be aware of factors that affect each other’s business objectives. MDR still requires that each notified body have a unique ID and CE Mark placed on the product, label, and packaging. The availability of this information will affect a company’s regulatory affairs, production, and supply chain organizations.

The European Commission, Industry and Trade Organizations are compiling a wealth of information to assist notified bodies and companies in developing strategies to become compliant with EU MDR by May 2020 and to sustain compliance in the future.

ISSUE 3

Post-MDR sustainability



The challenge

66% of survey respondents have yet to develop a plan for post-MDR sustainability. Since sustainability requires strict timelines, detailed data analysis/review, and cross-functional collaboration, it is imperative that organizations think about some of the most significant impacts on their long-term success after obtaining their CE mark and declaring MDR compliance.



What to do now

1. Develop clinical evaluation reports

40+% of all survey respondents noted that preparing MEDDEV 2.7.1 Revision 4 Clinical Evaluation Reports was one of the largest barriers to compliance. This is of concern since one of the central tenets of EU MDR is to ensure the health and safety of EU citizens using medical devices. Therefore, any medical device sold in Europe must have an up-to-date CER as part of its Technical File in order to receive its CE mark.

The CER must, at a minimum:

- Adhere to MEDDEV 2.7.1 Revision 4 requirements.
- Support all claims made on the device.
- Support the intended use and intended purpose of the device.
- Highlight the risk/benefit profile to the end-user of the device.

Further, the regulation puts a greater emphasis on supportive clinical data and equivalence. As new information and data points are available post-launch, manufacturers are expected to update their CER regularly and evaluate the claims above, intended uses, and risk/benefit profile of the devices. As MDR becomes law in 2020, equivalence claims will be more challenging to quantify, particularly for high-risk devices. Organizations' notified bodies would expect to see that, not only does a device have the same clinical and technical characteristics as the reference device, but also that the organization has access to data on that equivalent device. This means that, for implantable and Class III devices, an agreement must be in place to access the clinical and technical documentation of the device for which equivalency is claimed.

| | Class I | Class IIa | Class IIb | Class III |
|-------------|-----------|---|-----------|-----------|
| Risk Review | 5 years | 2 years | 1 year | 1 year |
| PMCF | | 1 year (implant) 2 years (non-implant) | | |
| PSUR | | 2 years | | |
| PMSP | | | | |
| CER | | | | |
| Tech File | As needed | | | |

To ensure that CER processes adhere to the regulation without causing bottlenecks, organizations must adopt strategies that outline not only the process of developing CERs themselves but also management and evaluation of data on an ongoing basis. To accomplish this, organizations should:

- Complete a gap analysis on existing CERs and define all data gaps.
- Define inputs to the CER, including PMS, risk/benefit, intended use, and indications.
- Develop an end-to-end Standard Operating Procedure so that the organization is equipped with appropriate sources and steps to address the complexities of a CER.
- Hold regular meetings at appropriate intervals to review risk data, plan for technical documentation updates, and review benefits/claims.

An established process will allow manufacturers to reinforce their CER processes to withstand additional review from notified bodies and, ultimately, ensure long-term patient safety and market access.

2. Comply with PMS Requirements

According to the survey, one of the most significant barriers to EU MDR compliance is the lack of guidance documents or standards for all the new required PMS reports. Specifically, 43% of respondents have not started to update their PMS procedures or create any templates for the reports, and 13% do not even have a PMS strategy in place. Only 11% have updated all the procedures and reports and can manage the 15-day reporting timelines, and 33% are in the process of finalizing their PMS plan and templates.

Since PMS requirements have become much more stringent under EU MDR as compared to MDD, organizations should update PMS procedures, and create the new documents, such as PSUR, PMSR, SCCP, etc. required under EU MDR. Due to lack of guidance around report development, it is important for organizations to keep a flexible approach when creating templates. Once the EU Commission releases templates for all the reports, organizations will be expected to use them. Organizations should also start communicating with their notified bodies about expectations on report completion. Finally, review and upgrade of systems may be required to meet the new timing parameters, especially the 15-day reporting timeline.

ISSUE 3

Post-MDR sustainability

Continued

3. Assign a Personal Responsible for Regulatory Compliance

The findings from last year's EU MDR survey are comparable to this year's when it comes to the person responsible for regulatory compliance (PRRC) role. The 2018 KPMG/RAPS survey indicated that 40% of respondents hadn't identified PRRC individual(s), 30% had identified the individual(s) but didn't document the role, and 9% were unaware of the requirement. This year, 26% of respondents have not identified PRRC individual(s), 40% have identified the individual(s) but haven't documented the role, and 4% are unaware of the requirement. Organizations need to clearly identify PRRCs, as well as their roles and responsibilities to carry out the requirements listed in EU MDR and meet the deadline. Additional considerations should be given to training and document repository access as part of the implementation strategy.



The long run

Even as organizations seek to comply with imminent EU MDR guidelines, it is critical to start planning and developing frameworks for long-term sustainability. In fact, the effort to sustain changes long term should be a continuous process as the regulation continues to evolve. It is possible to manage the additional workload that sustainability will require if organizations start planning now for the 2-5 years after application of the regulation.



ISSUE 4

Manage resources



The challenge

Survey results demonstrate that 91 out of the 230 respondents plan to increase headcount to address long-term EU MDR challenges. This approach may seem to be the easiest way to address these challenges, but it requires additional costs and has implications across the organization. Companies need to find ways to maintain their profit margins while addressing such challenges as maintaining and updating post-surveillance activities, reporting, and clinical evidence. Survey results demonstrate that 105 of 230 respondents have identified increasing responsibilities/ updating role definitions as a top challenge. Clearly, they need to address the impact of EU MDR efforts on employee engagement, quality of work, and resource constraints. Overall, there appears to be a gap in developing appropriate resource strategies for MDR sustainability: only 25% of survey respondents have fully developed a strategy, while the remaining 75% have not started to create a strategy or do not see any additional impact.



What to do now

Training and change management programs will be a necessary solution for 105 out of 230 survey respondents, and this is consistent across companies of all sizes. Although companies with established EU MDR programs may have robust strategies, it is critical to provide the necessary leadership and financial support to meet resource requirements. Therefore, role requirements and responsibilities must be clearly identified and divided across each impacted functional area, e.g., regulatory affairs, Quality, research development, operations, information technology, and supply chain. Such programs will help ease the complexity of the change and help manage the additional workload, employee morale, and new organizational business changes. Organizations should benchmark against their peers in order to support their own transitions, implementations, and business continuity efforts. Further, companies should seek to benchmark strategies to justify additional requests for funding. Finally, organizations should ensure that they continue to attend conferences and trainings, such as share forums or RAPS Convergence. There is immense value in conversations with peers and experts alike, as the entire industry is learning together – manufacturers, Notified Bodies, and consultants. Communicating with one another and sharing experiences are vital for calibration and application of resources.



The long run

In the short-term, companies may temporarily extend resource requirements to key functional areas. However, a truly prepared organization will ensure enough funding and additional resourcing for the long-term sustainability of MDR compliance. Therefore companies must be innovative in developing solutions to capacitate the rising expectations that come with EU MDR. Companies should develop a comprehensive change management program to execute the complex changes, alongside a detailed training program that can be ready for implementation at a moment's notice. It is critical to note that, without adequate planning and budgeting, EU MDR sustainability compliance efforts could have the unwanted impacts of strained resourcing, employee resistance, insufficient training, and communication failures across the organization.



Conclusion

The good news is that there is still time to accomplish all of the above and more, if companies work smart.

While the biggest challenge may be securing the resources and budgets to ensure that all pieces of the puzzle can be addressed, it will likely be helpful to position your EU MDR effort with leadership as more than just a regulatory obligation. Companies should instead reframe their EU MDR initiatives as an opportunity to simultaneously transform their organizations' processes, products, systems, and structures—a mindset shift that will have far-reaching value, long after compliance is achieved.

About KPMG

KPMG is a leading professional services firm with senior healthcare and life sciences practitioners dedicated to regulatory affairs, data & analytics, R&D and commercial strategy, risk consulting, and M&A.

Our *one firm* approach to client engagements results in an enterprise-wide view from strategy through results. In particular, our life sciences advisory team focuses on providing strategic support to pharmaceutical and medical device companies seeking to comply with regulatory initiatives and assists them in anticipating, navigating and balancing the myriad of issues that arise when undertaking a compliance project.



About RAPS

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products.

RAPS tracks regulatory developments and evolving professional competencies, and uses the latest information to develop tools and resources to meet the current and emerging needs of regulatory professionals.

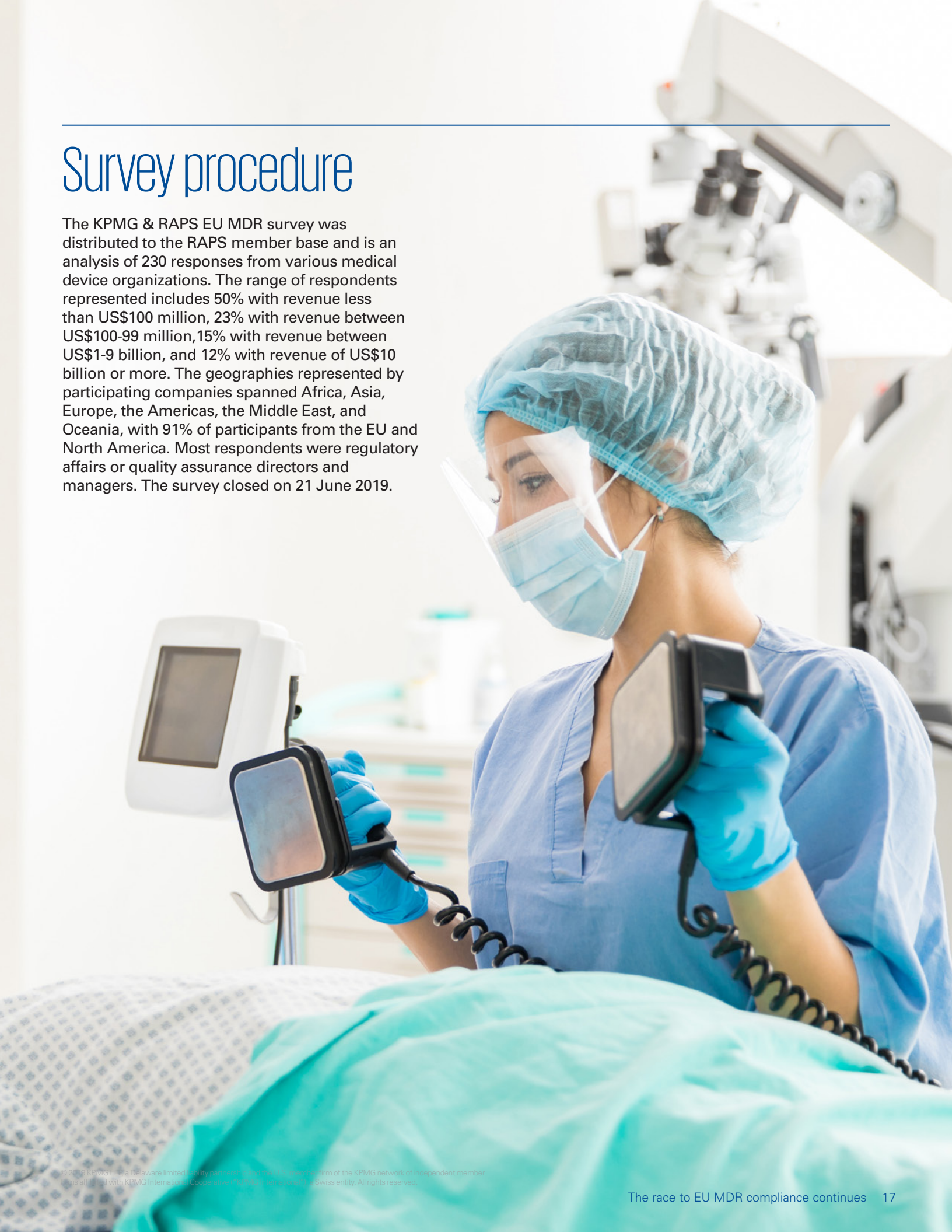
We connect the global regulatory community and empower professionals to share knowledge, ideas and expertise with one another. Both online and in person, we provide multiple opportunities for discussion, networking and relationship building among those based in disparate parts of the world or within the same local area.

We also deliver relevant regulatory news and analysis for busy professionals, and informational and educational resources for those who need a deeper understanding on key topics. As the need for qualified regulatory professionals continues to grow around the world, we help promote a competent regulatory workforce. RAPS created and continues to support Regulatory Affairs Certification (RAC), the profession's only accredited post-academic credential.

RAPS helps regulatory professionals effectively communicate the vital role they play in ensuring safe and effective healthcare products for patients and healthcare providers—giving them a voice in important conversations within their organizations and beyond, as they are increasingly being called upon to play leading roles.

Survey procedure

The KPMG & RAPS EU MDR survey was distributed to the RAPS member base and is an analysis of 230 responses from various medical device organizations. The range of respondents represented includes 50% with revenue less than US\$100 million, 23% with revenue between US\$100-99 million, 15% with revenue between US\$1-9 billion, and 12% with revenue of US\$10 billion or more. The geographies represented by participating companies spanned Africa, Asia, Europe, the Americas, the Middle East, and Oceania, with 91% of participants from the EU and North America. Most respondents were regulatory affairs or quality assurance directors and managers. The survey closed on 21 June 2019.



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