The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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Micro and Small Enterprise Considerations.

Introduction

Micro and small medical device and in vitro diagnostic manufacturers form a critical component of the European medical technology ecosystem. The Commission's own estimate, page 1 of COM (2025) 1023 proposal, indicates that approximately 90% of manufacturers are SME's, the majority of which are micro and small enterprises. They are an important source of innovation, niche clinical solutions, and patient access to specialised technologies. Many of these manufacturers operate with limited product portfolios, often a single product line, and are highly dependent on predictable and timely market access under the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) frameworks for their commercial viability and survival.

The ongoing revision of the European medical device regulatory framework reflects a shared policy objective: to improve system efficiency, increase predictability, and better support smaller manufacturers. Among the proposed measures is an expectation that notified bodies offer significantly reduced conformity assessment fees, up to a 50% discount for micro and small enterprises.

This proposal risks unintended consequences. It does not sufficiently account for the practical realities of conformity assessment activities, the actual resource burden involved in assessing less mature regulatory systems, nor the financial constraints under which notified bodies themselves operate. A sustainable regulatory ecosystem requires that support measures for small manufacturers are carefully designed so that they address root causes of regulatory difficulty without transferring disproportionate operational and financial risk to notified bodies, whose designation, competence, and independence are fundamental to patient safety and system credibility.

Problem Statement

The proposal for mandatory or expected fee discounts by notified bodies for micro and small medical device manufacturers (page 56, amendment to article 50. The proposal is 50% reduction for micro, 25% reduction for small and a deferment of fees until after conformity assessment is completed) raises substantial concerns regarding fairness, feasibility, and system sustainability.

Evidence from conformity assessment practice consistently shows that micro and small manufacturers often require significantly greater regulatory support and assessment effort than larger, more established organisations. This is typically reflected in:

- Higher volumes of clarification questions and follow-up interactions during technical documentation assessment,
- Increased numbers and complexity of non-conformities identified,

- Repeated cycles of resubmission due to immature or incomplete quality management systems and technical files.

These challenges are frequently attributable not to a lack of commitment by small manufacturers, but to structural limitations and lacking experience. Many micro and small enterprises have limited embedded regulatory affairs expertise. This situation is likely to be further exacerbated by the proposed removal of the requirement in Article 15 for micro and small enterprises to have a PRRC within the organisation, thereby reducing a critical mechanism intended to ensure regulatory competence at source.

In addition, clinical investigation planning and execution represent one of the most resource-intensive aspects of the conformity assessment process, both in terms of time and financial investment. For micro and small manufacturers in particular, the associated costs are sometimes unachievable, placing a disproportionate burden on organisations with limited financial and operational capacity. These costs are further compounded by the extended duration over which clinical investigations are conducted, as well as the specialised personnel and infrastructure required to design, manage, monitor, and analyse such studies.

This challenge is exacerbated by a lack of early regulatory clarity. In many cases, micro and small manufacturers must commit significant resources to clinical evidence generation without sufficient certainty that the chosen study design or evidence strategy will ultimately meet the General Safety and Performance Requirements set out in Annex I of the Medical Device Regulation. This uncertainty is often linked to limited in-house regulatory expertise, making it difficult for smaller organisations to confidently align their clinical strategies with regulatory expectations from the outset.

As a result, there is a substantial risk that costly and time-consuming clinical investigations may need to be repeated, adapted, or supplemented, further increasing the financial and operational strain. Addressing this issue is therefore critical, not only to alleviate the burden on smaller manufacturers, but also to improve the overall efficiency, predictability, and accessibility of the regulatory system.

At the same time, notified bodies operate under highly constrained economic and regulatory conditions. They face increasing designation and oversight requirements, rising liability exposure, and obligations to recruit and retain scarce technical and clinical experts. The cost of conformity assessment is fundamentally driven by expert time and procedural rigor, not the size of the economic operator. Imposing substantial fee reductions in cases where assessment effort is demonstrably higher risks undermining notified body capacity, incentivising risk, avoidant behaviour, or unintentionally reducing access to assessment service, contrary to the goals of the MDR and IVDR.

For many micro and small manufacturers, operating with a single product or a very limited portfolio is common. This model inherently increases financial vulnerability, as revenue is dependent on one primary source. Within this context, the requirements set out in MDCG 2019-6 impose a disproportionately high administrative and financial burden on them.

In particular, the expectation that notified bodies conduct annual sampling and repeated reviews of a device that has already undergone thorough assessment at the point of certification creates a recurring strain. This includes revisiting technical documentation even where only minimal updates, such as routine post-market surveillance data, are available. In practice, this level of repeated scrutiny often

provides limited additional value and results in an excessive regulatory burden for both manufacturers and notified bodies.This approach is also inconsistent when compared to the treatment of higher-risk devices covered under product certificates, where the depth and frequency of technical documentation reassessment may be less intensive following initial certification. As a result, manufacturers with a single device may be subject to more frequent and repetitive technical review than those managing multiple or higher-risk devices, despite the latter being inherently more complex.

The cumulative effect is a misalignment between policy intent and operational reality. Measures intended to support micro and small manufacturers risk destabilising notified bodies, increasing bottlenecks, and ultimately impairing market access for the very entities they aim to help.

A more sustainable approach is required, one that targets structural capability gaps, improves regulatory quality at source, fosters innovation, and enhances system efficiency without eroding the independence or financial viability of notified bodies.

It is also important to recognise, that consistency of approach across the system is critical to maintaining both regulatory integrity and a level playing field. Where individual notified bodies adopt divergent practices, particularly in relation to fee structures or perceived concessions, these approaches are quickly extrapolated by stakeholders and may create further issues across the wider system.

In this context, the principle of “same service, same cost” reflects not only economic reality but also the need to preserve fairness, independence, and confidence in conformity assessment activities. Any deviation from this principle risks introducing competitive distortion, undermining the collective position of notified bodies, and ultimately weakening the consistency that the European Commission itself expects under a harmonised regulatory framework. This further reinforces the need for solutions that are systemic, policy-driven, and implemented at EU or Member State level, rather than through ad hoc operational measures at individual notified body level.

Pragmatic Alternative Solutions to Support Micro and Small Manufacturers.

1. Formalise structured dialogue throughout the conformity assessment process and beyond

Structured dialogue is explicitly highlighted in the proposed MDR/IVDR reforms as a mechanism to improve predictability, proportionality, and mutual understanding in notified body engagement with micro and small manufacturers.

To further enhance these objectives, it is proposed that a structured dialogue opportunity be systematically offered to micro and small manufacturers each time a formal round of questions is issued during conformity assessment, at no additional cost. This dialogue, without constituting consultancy and with the clear option for the manufacturer to decline, would allow both parties to align on the intent, scope, and regulatory basis of the questions raised during the assessment, so the expectations of the notified body are clear from the start.

In practice, this would support early clarification of clinical, performance, and QMS expectations; reduce the risk of misinterpretation and iterative question cycles; and enable more efficient planning

of limited regulatory, financial, and personnel resources by small manufacturers. By ensuring that responses directly address notified body concerns at first submission, this approach has the potential to improve assessment efficiency, reduce avoidable delays, and enhance overall system effectiveness without compromising notified body independence or regulatory rigor.

From the perspective of micro and small manufacturers, the introduction of a mechanism comparable to the FDA's Q-Submission programme could deliver substantial benefits. These organisations often operate with limited regulatory experience and constrained resources, making early clarity on regulatory expectations particularly critical.

While due regard must be given to the provisions of Section 1.2. 3, of the Medical Device Regulation, specifically to safeguard the impartiality of notified bodies, it should nevertheless be possible to establish a structured, non-binding pre-submission process. Within such a framework, manufacturers could present proposed protocols, study designs, or testing strategies in advance of execution and receive high-level feedback from the notified body on their suitability to demonstrate conformity with relevant requirements.

Importantly, any feedback provided would not prejudice the notified body's independence, nor constitute a commitment to accept the final results. However, even non-binding input from a decision-making body would introduce a meaningful degree of clarity and predictability into the conformity assessment process.

For micro and smaller manufacturers in particular, this increased predictability would significantly reduce the risk of investing limited financial and operational resources in inadequate or misaligned evidence-generation activities. Ultimately, such an approach would support more efficient development pathways, improve the quality of submissions, and enhance overall access to the regulatory system for organisations with less established regulatory expertise.

2. Surveillance Requirements

A more proportionate and risk-based approach to post-certification sampling is essential, particularly for micro and small manufacturers of Class IIa and IIb non-implantable devices who have single product certificates. As currently reflected in MDCG 2019-6, notified bodies are expected to carry out regular and structured surveillance activities, including technical documentation sampling, as part of the certification lifecycle. However, in practice, this can lead to repetitive reassessment of devices that have already undergone a comprehensive and robust evaluation at the point of initial certification.

Regulatory oversight should instead focus on areas of genuine risk, such as significant design changes, emerging safety signals, or substantive updates to clinical or technical documentation that could impact the safety and performance of the device. Where a device has been thoroughly assessed and no meaningful changes or concerns have arisen, it should be possible for the notified body to justify a more targeted approach to subsequent sampling activities.

Introducing greater flexibility within the current framework would allow notified bodies to apply justified, risk-based discretion, avoiding unnecessary repetition of full technical documentation reviews on an annual basis. This would not only reduce administrative burden, but also better align

with the core principles of the Medical Device Regulation, which emphasise proportionality and risk-based decision-making.

Importantly, addressing this issue would correct an unintended imbalance in the current system, whereby micro and small manufacturers with single-device portfolios may be subject to more frequent and intensive scrutiny than manufacturers of higher-risk devices managed under product certification approaches. A revised, more targeted sampling methodology would ensure that regulatory effort is directed where it delivers the greatest value, rather than being expended on low-risk, duplicative activities. This would significantly improve efficiency across the conformity assessment system while maintaining high standards of safety and performance.

3. EU, Level Regulatory Capability Support Programmes

There is a clear need to establish EU or Member State, funded initiatives focused on strengthening regulatory capability among micro and small medical device manufacturers, particularly at the early stages of their MDR and IVDR onboarding.

In practice, manufacturers of this size often engage with the conformity assessment process too late in their development journey, which frequently results in significant challenges in generating adequate technical documentation and clinical evidence once regulatory review has commenced.

A more structured and proactive education framework could address this gap through initiatives such as formal MDR/IVDR onboarding programmes, non, binding and non, assessment, based pre, submission technical documentation readiness reviews, and standardised guidance addressing common non, conformities observed across assessments.

Supporting resources could include a series of structured webinars and educational materials that can be replayed on demand, enabling manufacturers to better understand regulatory expectations and allowing notified bodies to consistently direct stakeholders to authoritative reference materials when questions arise.

Such a programme would also support greater alignment of expectations between notified bodies, competent authorities, manufacturers, consultants, and other stakeholders, thereby improving overall submission quality and reducing avoidable assessment iterations. While the development of a coordinated education framework of this nature represents a significant undertaking and would require dedicated EU, level funding, (potentially through mechanisms such as Horizon Europe, NoBoCAP, or similar initiatives) notified bodies remain open to supporting and contributing their technical expertise to the development of content, recognising the long-term benefits this would bring to the efficiency, consistency, and sustainability of the regulatory system as a whole.

It is important to recognise that the challenges faced by micro and small manufacturers extend beyond notified body fees alone and are rooted in a wider, interconnected regulatory ecosystem. While reductions in notified body fees may provide some limited relief, such measures in isolation are insufficient to address the structural cost burdens associated with conformity assessment.

In particular, the provision of dedicated, non-repayable funding mechanisms at both EU and national levels are more meaningful to micro and small manufacturers. These funding programmes should

explicitly cover not only regulatory activities, but also the substantial costs associated with laboratory testing, clinical investigation, and contracted research organisations (CROs), which collectively represent a significant proportion of the overall financial burden for micro and small manufacturers.

Strengthening and expanding such funding instruments across Member States is therefore essential to achieving a more equitable and accessible regulatory environment.

Furthermore, it should be emphasised that reductions in notified body fees alone cannot constitute a comprehensive solution. Notified bodies, the majority of which operate as private entities, must retain the autonomy to determine whether and to what extent fee reductions can be applied, based on the sustainability of their own operational and capital expenditure structures. As a result, any discounts offered will necessarily vary between notified bodies and cannot be uniformly mandated at EU level without risking impacts on capacity, quality, or independence.

Equally, it is critical that other key actors within the conformity assessment ecosystem, including laboratories, CROs, and regulatory consultants are encouraged to adopt a similar approach. A coordinated effort across all stakeholders is required to ensure that cost reductions are meaningful, balanced, and sustainable. Without such a holistic approach, the cumulative financial barriers will remain disproportionately high for micro and small manufacturers, limiting their ability to successfully navigate the regulatory framework.

4. MDR/IVDR Consultants

Many micro and small medical device manufacturers rely heavily on external regulatory consultants to navigate the complexities of the MDR/IVDR. However, these consultants are frequently selected based on cost rather than demonstrated competence or relevant regulatory experience. This creates a significant vulnerability within the system, as manufacturers, particularly those with limited in-house regulatory expertise, are often not in a position to effectively assess or verify the quality and suitability of the advice being provided.

As a result, there is a tangible risk that manufacturers receive guidance that is incomplete, misinterpreted, or misaligned with regulatory expectations and notified body practices. This can lead to poor-quality submissions, prolonged review timelines, avoidable non-conformities, and ultimately increased costs and delays.

While highly experienced consultants, particularly those with prior notified body or equivalent regulatory assessment experience, can provide robust and well-aligned guidance, such expertise is not consistently accessible, nor easily identifiable by less experienced organisations.

This situation highlights a broader structural gap within the regulatory ecosystem. Unlike notified bodies, which are subject to stringent requirements for competence, qualification, and ongoing oversight, there are currently no equivalent, transparent mechanisms to ensure or demonstrate the competency of regulatory consultants. For micro and small manufacturers, this creates a challenging environment in which critical decisions rely on advice that may vary significantly in quality.

To address this, it would be beneficial to introduce mechanisms that provide an additional layer of assurance for manufacturers without compromising the independence of notified bodies. Structured

dialogue could be leveraged to allow notified bodies to review, at a high level, the adequacy and correctness of approaches or interpretations proposed by consultants. Such interactions would remain non-binding and focused on "what" is required rather than "how" to comply, thereby maintaining impartiality while offering valuable validation to manufacturers.

This approach would provide micro and small enterprises with greater confidence that the advice they are relying on is aligned with regulatory expectations, reducing the risk of costly missteps. This could significantly improve the consistency and quality of regulatory submissions at source, strengthen trust across the system, and deliver meaningful benefits for micro and small manufacturers.

5. Offer remote or hybrid audit options where appropriate

The broader and more systematic introduction of remote and hybrid audit models would deliver significant benefits for micro and small medical device manufacturers, particularly those with limited resources and have small or remote operational teams.

On-site audits often require substantial preparation, dedicated staff availability, and logistical coordination, which can place a disproportionate burden on smaller enterprises that may lack spare regulatory or quality personnel.

A risk-based and proportionate approach to remote or hybrid audits, considering factors such as device technology, long, standing market history, organisational maturity, and demonstrated regulatory compliance, would allow oversight activities to be tailored appropriately without compromising regulatory rigor.

Manufacturers with stable product portfolios, consistent quality management system performance, a strong compliance record, and no history of serious non, conformities, field safety corrective actions, or unresolved post, market concerns could be well suited to partially or fully remote audits. Such an approach would reduce travel and administrative costs, allow for more flexible scheduling, and better accommodate organisations with limited on, site staff or distributed teams. By aligning audit modality with actual risk and performance history, remote and hybrid audits can meaningfully reduce financial and administrative burdens for smaller manufacturers while preserving effective regulatory oversight, supporting predictability, and improving overall system efficiency.

6. Guidance and Template Harmonisation

A coherent and predictable regulatory system requires not only high, quality guidance, but also a clear and consistent pathway for how such guidance is applied in practice across different device types and regulatory stages.

The Medical Device Coordination Group (MDCG) has published an extensive and growing body of guidance intended to harmonise MDR and IVDR implementation, covering areas such as classification, borderline determinations, clinical evaluation, performance studies, and post, market requirements. However, without structured support, micro and small manufacturers in particular often struggle to identify which guidance is most relevant to their specific device or how multiple documents should be applied in combination, leading to misclassification, incomplete evidence packages, and avoidable assessment delays.

Actively guiding manufacturers in the appropriate and proportionate use of MDCG guidance, for example by mapping key documents to assessment stages and device categories, would significantly reduce regulatory uncertainty and align submissions with EU expectations from the outset. In parallel, closer collaboration between regulators, notified bodies, and industry stakeholders to develop harmonised technical documentation templates, anonymised examples of high, quality submissions, and clearer interpretations of commonly misunderstood requirements would further strengthen consistency and efficiency. Embedding these elements within a unified, formalised, and ideally digitised submission framework would represent a major step forward for the system as a whole, driving harmonisation, improving first, pass success rates, and reducing administrative burden for manufacturers of all sizes.

Importantly, while such measures would be particularly beneficial for micro and small enterprises with limited regulatory capacity, the advantages of clarity, consistency, and predictability would extend equally to larger manufacturers, notified bodies, and competent authorities, making this a foundational enabler of a more effective and resilient EU regulatory ecosystem.

Conclusion

Notified bodies fully support the objective of strengthening the position of micro and small manufacturers within the European regulatory framework and ensuring continued patient access to safe and effective medical technologies. However, the challenges faced by these organisations are structural and systemic in nature, extending far beyond notified body fees alone. Measures focused solely on fee reductions risk addressing symptoms rather than root causes, and may unintentionally undermine the capacity, independence, and sustainability of the conformity assessment system.

The analysis presented in this paper demonstrates that the primary barriers encountered by micro and small manufacturers relate to limited regulatory experience, high costs associated with clinical evidence generation and external services, variability in the quality of regulatory advice, and inefficiencies arising from disproportionate or repetitive conformity assessment activities.

Addressing these challenges requires a more balanced and ecosystem-wide approach. The most effective solutions lie in improving regulatory capability at source, increasing predictability of requirements, and ensuring that oversight activities are applied in a proportionate and risk-based manner. In this context, the measures proposed in this paper provide a targeted and practical path forward, including:

- Strengthening and formalising structured dialogue, including pre-submission interactions, to improve early alignment and reduce uncertainty;
- Introducing greater flexibility in post-certification surveillance and sampling, enabling notified bodies to apply justified, risk-based approaches and avoid unnecessary duplication;
- Establishing EU and Member State-funded programmes to support regulatory capability development and to offset the broader costs of clinical investigations, laboratory testing, and associated services;

- Improving transparency, consistency, and assurance in the use of regulatory consultants, including mechanisms for validation of regulatory approaches through structured dialogue;

- Expanding the use of remote and hybrid audit models where appropriate, reducing operational burden on smaller organisations;

- Advancing harmonisation of guidance, templates, and submission frameworks to improve clarity, consistency, and first-time quality of submissions.

Collectively, these measures address the underlying drivers of inefficiency and cost, while preserving the integrity, independence, and technical rigour of notified bodies. Importantly, they support a more equitable and accessible regulatory environment without introducing distortions or unintended consequences associated with mandatory fee reductions.

A sustainable and resilient regulatory system must be built on proportionality, predictability, and shared responsibility across all actors in the ecosystem. By focusing on these principles, the European framework can more effectively support innovation from micro and small manufacturers, while continuing to uphold the highest standards of patient safety and public health.