***NBs-MDRIVDR-Call-For-Evidence-DG-Connect***

Dear members of the European Commission, DG CONNECT O1, A2, G1, H2, H4,

Subject: Contribution to the Call for Evidence: Digital Omnibus (Digital Package on Simplification) - Specific challenges for Notified Bodies (NBs) in the context of the AI Regulation

The New Legislative Framework, which includes 30 product directives and regulations including the AI Act, MDR, etc., is a legislative framework for the promotion of the European market and the quality of CE marked products.

It is based on shared rules for the accreditation of conformity assessment bodies and market surveillance by the competent national and European authorities.

It applies to all regulated PRODUCTS (including software) made available for the first time in the European Union: the responsibility for the conformity of the products lies with the economic operators (manufacturer or provider-authorized representative-importer-distributor).

In some cases, for the verification of conformity, the manufacturer's declaration is not sufficient and accredited bodies and notified bodies are involved in the assessment of the product’s design, production, technical documentation, inspection, testing, full quality assurance (with periodic audit to assess and survey the quality system, including the risk management system).

Now that AI technology is transforming industry and products radically, an update in the framework is needed to take into account the challenges of digitalisation and complex value chains, sustainability, digital CE marking...

The AI Act is the 28th product legislation under the European New Legislative Framework, aiming to address the risks of AI and to foster trustworthy AI in Europe.

It is already built on the legal concept that whenever a matter is regulated by two rules, the more specific one should be applied first, avoiding double-regulatory burden.

Team NB welcomes the Commission's initiative to drive forward the simplification of the digital regulatory framework and reduce administrative costs for businesses as part of the Digital Omnibus. We strongly support the general objective of creating legal clarity and predictability, especially with regard to the optimal application of the recently adopted AI Regulation (Regulation (EU) 2024/1689).

We consider ourselves key contributors to the emerging digital ecosystem, as our work as Conformity Assessment Bodies (CABs/NBs) plays a vital role in ensuring the high level of health, safety, and fundamental rights protection envisioned by the AI Act.

Considering the challenges experienced during MDR/IVDR implementation by different stakeholders (authorities, NBs, manufacturers and providers), jeopardising enforcement and innovative devices availability to patients, we envisage a smooth and uniform implementation under the existing governance, the existing framework, the existing notifications in NANDO and designation process with a centralised oversight and limited duplication of efforts.

Ensuring a uniform assessment of Notified Bodies by Member States’ Competent Authorities is essential to maintain consistency, credibility, and trust in the European regulatory system. Divergent interpretations or approaches can lead to unequal conditions for Notified Bodies and manufacturers, ultimately affecting market fairness and patient or user safety. A harmonized assessment process promotes transparency, mutual recognition, and efficiency across the EU. By aligning expectations and practices, Competent Authorities and Notified Bodies can strengthen the overall quality and integrity of conformity assessment activities.

Our contribution addresses a key aspect that has so far received limited attention in the simplification debate, one that directly impacts on the economic sustainability of Notified Bodies and, in turn, the effective enforcement of the AI Regulation: the high conformity assessment costs resulting from varying levels of preparedness among economic operators due to frequent changes and/or extensions to regulatory requirements and their interpretations.

The AI Regulation will apply directly from August 2026 for Annex III listed AI Systems or August 2027 for Manufacturers of Medical Devices and IVD under Annex I AIA listed harmonization legislation. It provides for the involvement of independent conformity assessment bodies (CABs): Notified Bodies (NBs) for high-risk AI systems. Member States are obliged to set up the necessary procedures for the assessment, designation, and notification of these bodies and to ensure their supervision. The existence of a robust and functional network of NBs is essential for market surveillance and legal predictability for companies, especially for SMEs that must apply the rules with limited resources.

Economic Operators and Notified Bodies as independent entities require a clear, stable, and predictable environment to efficiently fulfill the legal requirements set out. If this is not the case, we observe economic operators struggling with providing documentation of high-risk AI systems that are complete and fully compliant, which delays the conformity assessment process as incomplete and/or not fully compliant submissions often necessitate additional review cycles, clarifications, and coordination, leading to increased demands on document management and technical expertise within Notified Bodies. Delayed conformity assessments in turn may lead to a shortage in product availability.

Additionally, we observe that costs for NBs increase considerably to uphold qualifications for specialists required for NBs as legally required. Extensive personnel resources are required to conduct the conformity assessment activities if qualification requirements become unnecessarily detailed. In the interest of simplification, it could therefore be questioned what level of detail is necessary to ensure the high level of safety, health, and fundamental rights protection envisioned by the AI Act.

Based on our experience we fear following negative effects, which contradict the objectives of the Digital Omnibus:

* Jeopardising enforcement: A lack of NBs would massively hinder the optimal application of the AI Regulation and thus compliance with safety standards in the internal market.
* Obstacle to innovation: Long waiting times or a lack of specialized NBs hinder the market launch of innovative AI systems and impair the competitiveness and innovative strength of the digital sector in the EU.
* Capacity issues: A shortage of NBs could lead to an imbalance in the Member States and further exacerbate the already existing fragmentation in the national application of digital rules.

Team NB and NBCG-Med therefore suggest using existing frameworks for appointing NBs under the regulations to avoid duplicate efforts for NBs. NBs are already certifying AI applications and are under surveillance by Competent Authorities. This approach would allow continuity for this sector, which has already high patient safety standards and is in transition to even more elaborate regulatory requirements.

Furthermore, economic safeguards against additional costs are essential in order to ensure that NBs can fulfil their sovereignly delegated tasks independently, impartially, and without bias.

We therefore call on the Commission to examine the introduction of explicit reimbursement or compensation mechanisms as part of the Digital Omnibus or subsequent measures.

These mechanisms should:

* include clear rules on the billing of additional work caused by repeated testing, incomplete documentation, or delays on the part of the manufacturer.
* ensure that the costs incurred are fully covered in order to prevent notified bodies from having to cease their activities for economic reasons.

To maintain consistency, credibility, and trust in the European regulatory system, it is important to ensure a uniform assessment of Notified Bodies by Member States’ Competent Authorities.

Divergent interpretations or approaches can lead to unequal conditions for Notified Bodies and manufacturers, ultimately affecting market fairness and patient or user safety. A harmonized assessment process promotes transparency, mutual recognition, and efficiency across the EU. By aligning expectations and practices, Competent Authorities and Notified Bodies can strengthen the overall quality and integrity of conformity assessment activities.

The Digital Omnibus is an important opportunity to reduce bureaucratic burdens. This includes ensuring the efficiency and sustainability of those actors (including NBs) responsible for conformity assessment.

We ask the Commission to consider both measures to ensure a uniform assessment and the economic stability of Notified Bodies as an integral part of the simplification and enforcement strategy in the Single Market and to consider corresponding reimbursement schemes in the context of the envisaged proposals to implement a strategy for the Digital Omnibus.