The European Association of
Medical devices Notified Bodies

TEAM-NB A.I.S.B.L.
Rue Bawepuce 20
B – 4140 Sprimont - BELGIUM
Phone: +32 475 85 40 45

E-mail: assistant@team-nb.org
Web: http://www.team-nb.org
IBAN BE09 3401 5174 8757
VAT BE 0864 640 677

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TEAM-NB Position Paper

New MDR Transition Timelines and Notified Body Capacity

Structure

1. Executive Summary

Regulation (EU) 2023/607, adopted in March 2023, amends the transitional provisions for certain medical devices covered by the Medical Device Regulation (EU) 2017/745 (MDR). With this amendment authorities reacted to the fact that the transition from the previous directives (MDD/AIMDD) towards the MDR progressed much slower than anticipated. Already by the end of 2021, it became evident that it was impossible to recertify all medical devices currently on the market within the remaining timeframe before the original transition deadline on 26 May 2024. This presented an imminent threat to cause a severe shortage of medical devices on the European market potentially putting the health of European patients in jeopardy. Notified bodies welcome the generous extension of the transition timelines and are confident that they could transition all remaining certificates within the given timeframe.

However, it is not just up to notified bodies to facilitate a successful transition. Many manufacturers are not applying for MDR certification in time and a lot of the received applications contain incomplete MDR technical documentation (see chapter 3.2.2.). Additionally, other factors hamper the effective use of available notified bodies capacity. Regulators play a crucial role here, as a lot of capacity is needed to constantly train notified body staff on new guidance documents, which are sometimes only published quite late (see chapter 3.2.3.).

The new transitional provisions are giving manufacturers more time to bring their products into compliance with MDR. The introduction of specific requirements to benefit from the extended deadlines are aimed at ensuring that manufacturers are actively working towards the transition. Additionally, the implementation of staggered deadlines will help to reduce overwhelming peak deadlines, potentially leading to a smoother and more manageable transition process. However, the deadline extension alone will not ensure a successful transition. Notified bodies urge manufacturers to submit their complete MDR application as soon as possible, and to not wait until the last moment as new peaks in workloads for notified bodies could arise (see chapter 3.3.).

From the outset of the MDR, it was clear that the new requirements would make the certification process more extensive. Thus, the demand for notified body capacity would increase and manufacturers would need to allocate more resources to fulfil their new obligations (see chapter 4.1.). Consequently, notified bodies have invested extensive time and resources to expand their capacity. They have hired a considerable number of additional staff members. Furthermore, notified bodies have actively engaged in training their existing and new personnel to ensure they possess the necessary knowledge and competence to carry out conformity assessments and certifications under the MDR (see chapter 4.2.). Moreover, notified bodies dedicate most of their time to small and medium-sized enterprises (SMEs), allowing smaller manufacturers to transition (see chapter 4.3.).

The establishment of sufficient new notified body capacity is undoubtedly a crucial element in facilitating a successful transition to MDR. Nevertheless, notified bodies are currently confronted with several challenges that consume valuable resources, rather than focusing on their primary regulatory tasks. The publication of MDCG 2022-14 has provided a positive starting point in addressing some of these challenges.

Notified bodies capacity could especially benefit from the following (see chapter 4.4.):

- **Implementation of MDCG 2022-14 measures (see chapter 4.4.1.)**
  Although the MDCG 2022-14 document has made notable progress in addressing various challenges for notified body capacity, several critical deliverables are still pending.

- **Stable regulatory environment (see chapter 4.4.2.)**
  Limiting the amount of additional new interpretations/requirements posed on notified bodies by MDCG documents will free up valuable resources, that are currently bound by assessing the documents, adapting internal processes, and training staff accordingly.

- **Shorter timelines for notified body designation (see chapter 4.4.3.)**
  Faster designation of new notified bodies will increase the overall capacity for certification, enabling a more efficient transition process.

- **Alternative means of demonstrating competencies (see chapter 4.4.4.)**
  Capacity expansion in designated notified bodies would be facilitated by allowing alternative means of demonstrating staff competences.

- **Facilitate and support the harmonisation efforts of notified bodies (see chapter 4.4.5.)**
  Notified bodies have started to take measures to harmonize procedures. These efforts are currently carried out through extensive coordination work by NBCG-Med and TEAM-NB. Establishing a technical secretariat to support and coordinate the vital harmonization work of NBCG-Med would further enhance progress in this domain.

- **Complete and timely applications from manufacturers (see chapter 4.4.6.)**
  Timely and complete applications from manufacturers are vital for notified bodies to efficiently certify all medical devices under MDR. Regulatory authorities can aid this process by offering clear, timely and concise guidance.

- **Availability of experts fulfilling the new requirements (see chapter 4.4.7.)**
  The MDR implementation has raised the demand for experts in the clinical, regulatory and technical area. However, finding enough qualified individuals has become challenging for manufacturers, regulators and notified bodies alike. Notified bodies could benefit from streamlining authorization requirements.

2. Introduction

The medical device Regulation (EU) 2017/745 (MDR) came into force in 2017 to supersede the MDD (Medical Device Directive) and AIMDD (Active Implantable Medical Device Directive). The development of this new regulation was focused on addressing perceived shortcomings of the directives and the overall aim was to better ensure the safety of medical devices. This led to an expansion of the requirements for economic operators, notified bodies and the overall regulatory process of conformity assessment. The introduction of MDR also defined a transition period split into several sequential phases and with specific provisions for different device risk classes. By the end of this transition period, all products needed to be certified under MDR, including all legacy devices previously placed on the market under MDD and AIMDD, that are safe and fulfill the new requirements.

In March 2023 the amending Regulation (EU) 2023/607, that extends the transitional provision, was published. This allows for additional time for manufacturers to submit their application for MDR and simultaneously introduces a set of pre-conditions for manufacturers to qualify for the extension. Notified bodies welcome the generous extension of the transition timelines and are sure that they could transition all remaining certificates within the given timeframe. However, this is not only up to the notified bodies.

This whitepaper discusses why the new transitional periods were necessary and the consequences that notified bodies expect from this change. Furthermore, this paper elaborates on the current status quo of notified body capacity and measures that will help to secure a successful transition.

3. New timelines and their consequences

3.1. Overview of the new timelines

The amending regulation extends the MDR transition timelines and gives manufacturers more time to bring existing products into compliance with the MDR. In the meantime, manufacturers can continue to place their products on the market, if they comply with certain conditions. More time will only be granted for products that are safe and for which manufacturers have already taken steps to transition to MDR. Additionally, an application for an MDR certificate to a notified body must be submitted by 26 May 2024 at the latest and the contractual agreement with the notified bodies must be concluded by 26 September 2024 at the latest.

Depending on the different risk classes of devices the following new transition periods apply:

Transition Deadline	**Affected Devices**
26 May 2026:	Custom-made implantable devices in class III
31 December 2027:	Higher-risk devices *This includes Class III devices and Class IIb implantable devices, excluding sutures, braces, dental fillings, dental braces, dental crowns, screws, wedges, plates, wires, pins, clips and connectors.*
31 December 2028	Medium and lower risk products *This includes other class IIb products, class IIa products and products of classes Is, Im, Ir.*
No extension:	Class I devices (other than Is, Im, Ir)

The sell-off period for existing products previously specified in the Medical Devices Regulation (MDR Art.120(4)) and In Vitro Diagnostic Medical Device Regulation (IVDR) Art 110(4) has also been abolished to allow medical devices already placed on the market to be made available beyond the original date of May 2025.

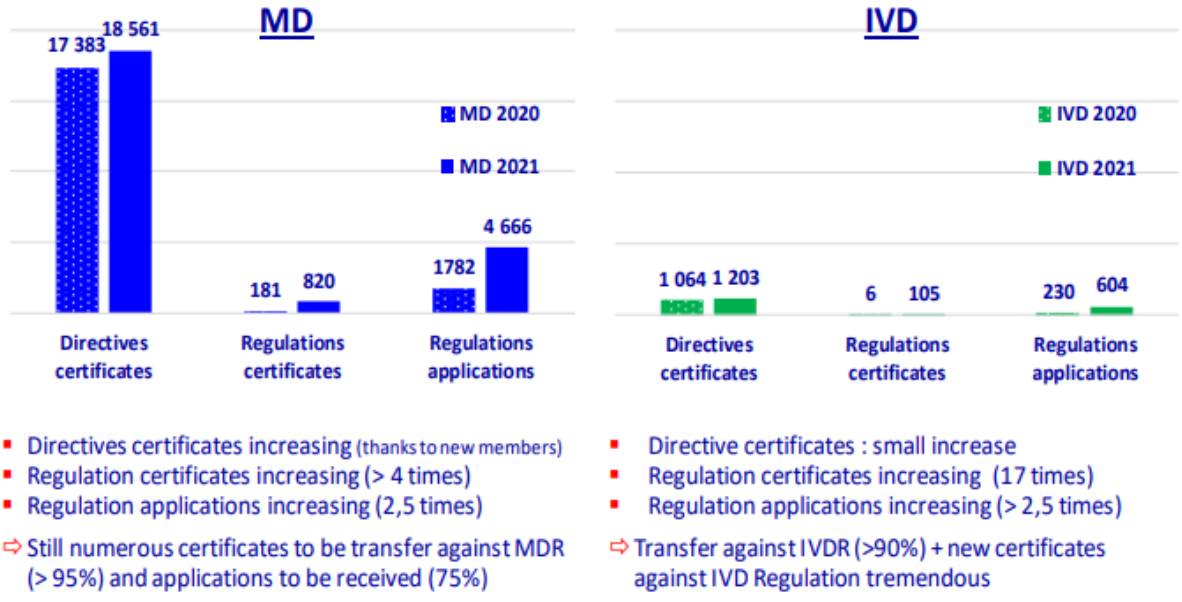
3.2. Necessity of the new transitional provisions

3.2.1. Risk of medical device shortages

The implementation of the MDR has faced several challenges since coming into force in 2017. The transition of devices placed on the market under MDD/AIMDD to MDR has progressed much slower than originally anticipated. At the end of 2021, notified bodies expressed great concern regarding the insufficient transition rate. They emphasised that, at the current speed, not all devices currently on the market, that are safe and fullfill the new requirements, could be reviewed under the MDR, before the expiry of the MDD/AIMDD certificates or the end of the original transitional period on 26 May 2024 *(Team-NB 2021b, p1-2)*. The high number of certificates at risk of expiry, presented an imminent threat to cause a shortage of medical devices on the European market.
Securing the availability and access of medical devices for European patients, needs to be the highest priority for all actors involved in the production, certification, and oversight of medical devices in the European Union. Therefore, notified bodies welcome Regulation (EU) 2023/607 amending the transitional provisions for certain medical devices.

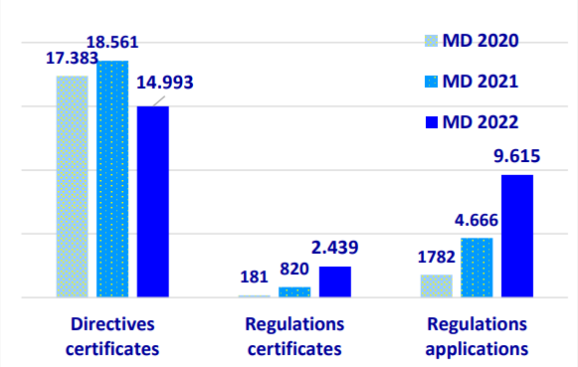
3.2.2. Delayed and incomplete applications

While the deadline for compliance on 26 May 2024 approached fast, the number of applications from manufacturers to notified bodies did not increase as expected. Sector surveys, conducted by TEAM-NB in 2021 and 2022, revealed that only a small percentage of certificates had successfully transitioned. While the number of released certificates and applications to notified bodies increased between 2020 and 2021, the relative number of MDR conformity assessments remained low. In 2020 only 181 MDR certificates had been issued, while in 2021 the number grew to 820 certificates. Similarly, the number of applications increased from 1 782 in 2020 to 4 666 in 2021. By the end of 2021, it was estimated that over 95% of directive certificates had yet to be transferred into MDR. Additionally, for more than 75% of all MDD/AIMDD certificates, applications for MDR conformity assessments had not been submitted to the notified bodies (TEAM-NB 2022a, p.6).
This data clearly demonstrated a lack of progress in the transition process, prompting notified bodies to once again emphasize the urgency for manufacturers to prioritize and expedite their applications. This urgency was intensified by the fact that valuable capacity within the notified bodies was not utilized (TEAM-NB 2022b, p.33).

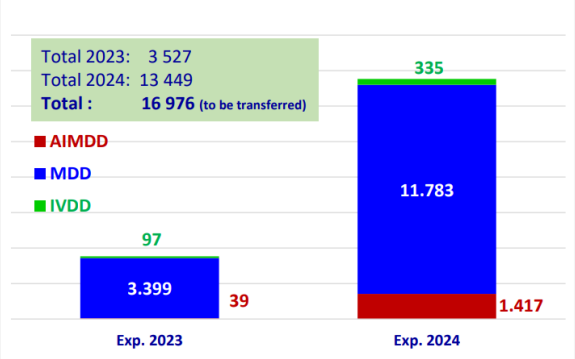


(Source of figure: TEAM-NB 2022a, p.6)

Throughout 2022, the progress continued to be alarmingly slow, making it impossible to complete the transition prior to the original MDR deadlines. At the end of 2022, only 14% of issued certificates were in accordance with the MDR, when compared to the total number of directive certificates. On a positive note, the number of applications increased significantly, accounting for 63% of the remaining directive certificates *(TEAM-NB 2023, p6-7)*. However, it is important to note that many of these applications include a smaller scope than the one covered by the directive certificates. The application for smaller scopes can be attributed to a lack of readiness of MDR technical documentations for numerous devices as well as a staggered approach taken by manufacturers to certify their product portfolio gradually. Many applications received by notified bodies are incomplete and additional information needs to be requested before the assessment can begin *(TEAM-NB 2023, p5-6)*.
Additionally, the numbers of the TEAM-NB survey are most likely underestimating the actual challenge, because MDR is expected to significantly increase the total number of certificates compared to the directives (e.g. each class IIb implantable device will require a separate certificate, Basic UDI-DI requirements for grouping devices may also contribute to an increased number of certificates *(TEAM-NB 2023, p.7))*.



(Source of figure: TEAM-NB 2023)



(Source of figure: TEAM-NB 2023)

The anticipation of a peak in applications towards the original 2024 deadline has been a significant concern for notified bodies. It was evident that the number of applications expected to be received in 2023 and 2024 would exceed the available processing capacity. This would have resulted in the expiration of certificates, withdrawal of products from the European market, and subsequent supply bottlenecks of medical devices for European patients. The expected peak was also amplified by the decision in early 2020 to postpone the application date of the MDR from 2020 to 2021, without changing the end of the transition period. Due to this postponement, a great number of manufacturers applied for an extension of their MDD/AIMDD certificates. Notified Bodies supported this and successfully renewed most of the directive certificates. This meant that European patients benefitted from the availability of safe devices while manufacturers completed their transition to MDR (albeit slowly). But this also meant that the MDR work started in earnest only in 2021. These extended MDD/AIMDD certificates would all remain valid until the end of the original transition period in 2024. This added to the anticipated peak in applications towards the deadline, creating an unmanageable workload for notified bodies.

3.2.3. MDCG documents and unharmonized national procedures

Since the MDR came into force, over 80 documents and 1500 pages of guidance have been developed by the MDCG *(European Commission 2023a).* These documents have played a crucial role in aiding all stakeholders in comprehending and consistently implementing the requirements. However, the implementation of such a vast array of guidance documents poses significant challenges to notified bodies and manufacturers. The sheer volume of these guidelines necessitates an extensive allocation of resources.

While the comprehensive nature of the guidance documents is undoubtedly beneficial for ensuring compliance with the MDR, it is important to consider the practical limitations associated with their implementation. Notified bodies need time to assess all documents and translate them into their internal processes. Lengthy discussions with manufacturers can prolong this procedure. This, in turn, also leads to a seemingly unharmonized approach, as notified bodies need shorter or longer timeframes to adopt the necessary changes. Some of the guidance documents are already at their second or third revision, demonstrating the complexity of the MDR regulatory framework.
Additionally, the lack of harmonization among member states in certain areas in interpreting the regulation and subsequently binding notified bodies to their national interpretation, is creating further confusion and challenges.
Notified bodies need a stable regulatory environment to dedicate all their resources to the MDR transition.

3.3. Benefits and limitations of the new timelines

The new transitional provisions present a renewed opportunity for manufacturers to transition their devices to the MDR. The introduction of staggered deadlines helps to reduce overwhelming peak deadlines, not just during the transition process but also regarding future re-certification timelines. The gradual MDR certification of medical devices, will also lead to a more evenly distributed pattern of certificate expiry dates and consequently re-certification. Additionally, manufacturers are now obligated to submit their applications earlier and demonstrate progress towards MDR compliance. This proactive approach helps to streamline the transition and ensures that manufacturers are working towards meeting the requirements of the new regulation. The amending regulation also allows notified bodies a view into manufacturers' transition plans and in particular into the availability of technical documentation. This paints a clearer picture for notified bodies of awaiting workload throughout the prolonged transition period, and thus allows them to plan accordingly.

However, extending the deadline alone will not ensure a successful transition. Notified bodies are deeply concerned as they see the numbers of MDR applications drop again as of the end of 2022, when first drafts of the amending regulation, extending of the transition timelines, were circulated. Notified bodies are calling on all manufacturers to liaise with their notified bodies and to submit their applications now to successfully manage this transition together.
Although the amending regulation is aimed at a staggered approach, it still contains fixed deadlines (application submission in 2024, finalisation of certification processes in 2027/2028). If manufacturers were to wait until the last moment to submit their application or technical documentation, they could again create challenges for notified body capacity.
Notified bodies have made extensive efforts to expand their capacities, already before the extended timelines, and are confident that they will be able to certify all medical devices under the MDR before the new deadlines. However, numerous obstacles continue to impede the work of notified bodies. The next chapter will elaborate on the current status quo of notified body capacities and necessary measures to make sure that notified bodies can use their time effectively.

4. Notified Body Capacity

4.1. Increased demand for notified body services

The MDR significantly extended the requirements for manufacturers to place their devices on the European market. In comparison to the MDD, the MDR introduced substantially more comprehensive requirements for medical devices.
The definition of medical devices and active implantable medical devices has been expanded to include devices that were not previously covered under the MDD and AIMDD. MDR's stricter risk classification requirements resulted in the reclassification of certain devices into higher-risk classes and necessitate

greater amounts of conformity assessment. Additionally, the MDR significantly increases the demand for clinical evidence.
Furthermore, the MDR does not allow any "grandfathering". This means, all data stemming from conformity assessments conducted under the previous MDD/AIMDD cannot be utilized as a reference for assessing devices under the MDR. The underlying rationale behind this approach is to ensure that each medical device undergoes a fresh evaluation in accordance with MDR, thereby upholding the

highest standards of safety and efficacy. However, this strict non-grandfathering policy has led to an enormous workload for notified bodies.
Consequently, it was apparent from the start that these changes would extend the certification process and require manufacturers and notified bodies to allocate additional resources to fulfil new obligations.

4.2. Extension of notified body capacities

Over the past years, notified bodies have made substantial efforts to expand their operational capacity. This included not only the extensive recruitment of additional personnel, but also a major investment into training of both existing and new staff. For an overview of the notified body staff development see the TEAM-NB sector surveys from 2020, 2021 and 2022 *(TEAM-NB 2021a, TEAM-NB 2022a, TEAM-NB 2023).* Despite these efforts, notified body capacity could still benefit from streamlining authorization requirements (see chapter 4.4.7).

4.3. Capacities for SMEs

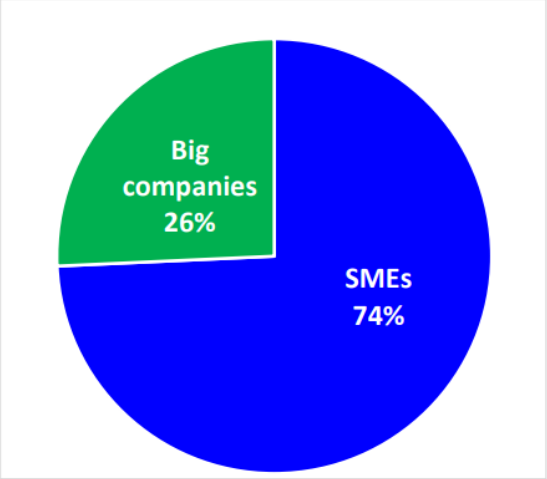
Notified bodies are often criticized for prioritizing larger clients over small or medium-sized enterprises (SMEs). However, the TEAM-NB survey from 2022 demonstrates that notified bodies already allocate 74 % of their time to SMEs *(TEAM-NB 2023, p.4).* Moreover, notified bodies offer trainings for manufacturers, ensuring that SMEs are able to participate at discounted rates.

- **Access to Notified Bodies by SMEs are taken into accounts by Members.**

Indeed, 27 members on 29 responses indicate that SMEs represent minimum 50% of their activities

and

as a mean of all responses, SMEs are representing 74% of their activities.



(Source: TEAM-NB 2023, p.4)

4.4. Further measures to foster notified body capacity

4.4.1. Implementation of MDCG 2022-14 measures

Regulators have acknowledged the significantly increased workload for notified bodies under the new regulation and issued MDCG 2022-14, identifying and initiating measures to unburden notified bodies and use the existing capacity as efficiently as possible. Among the measures already set in motion are the possibility to make use of hybrid audits and the opportunity to combine audits under the directives and the regulations for legacy devices and the abandonment of TD sampling for devices under the directive. Another measure freeing up resources of notifies bodies is the prolongation of the timelines for first re-assessment of designated notified bodies from 3 to 5 years. Additionally, the possibility to leverage evidence from previous assessments under the directive for MDR evaluations will free up more notified body capacity, once it will be endorsed by the authorities *(state of play: 19 July 2023).*

Although MDCG 2022-14 has made notable progress in addressing various challenges, several critical deliverables, aimed at increasing notified body capacity are still pending, and should be promptly implemented:

- **Administrative workload reduction (MDCG 2022-14, action 4)**
  Action 4 of the measures in MDCG 2022-14 promises a review of the MDCG guidance documents to identify areas in which administrative burden for notified bodies could be eliminated. Despite notified bodies sharing a list of around 40 concerns with regulators in August 2022, no significant outcomes have been achieved thus far.

- **EUDAMED (MDCG 2022-14, action 5)**
  Delays in the implementation of EUDAMED, the European database for medical devices, has led to considerable challenges for notified bodies in meeting their newly defined documentation obligations under the MDR. In the absence of EUDAMED, notified bodies have continued to feed their data into national data bases. As these data bases are not connected with EUDAMED, notified bodies are bracing for a resource consuming process to transfer the data once EUDAMED becomes functional. Additionally, the delay of EUDAMED prohibits the chance to derive meaningful insights and learnings from the system. The anticipated advantages of machine-to-machine (M2M) technology, which hold significant potential for enhancing efficiency and analysis, have yet to be realized due to the ongoing delay in the database's deployment.

- **Timely addition of designation codes (MDCG 2022-14, action 9)**
  Overall notified body capacity could benefit from an efficient process for the extension of designation scope for already designated notified bodies. MDCG 2022-14, action 9, indicates that regulators are exploring means to “add codes to the designation of notified bodies in a timely manner” *(Medical Device Coordination Group 2022).* However, currently there has been no visible progress in the timely addition of designation codes to the notified bodies.

- **Structured dialogue (MDCG 2022-14, action 15)**
  The establishment of structured dialogues between regulators and stakeholders is crucial for effective communication and addressing emerging challenges. The development and implementation of structured dialogue mechanisms are still to be started.

4.4.2. Stable regulatory environment

The MDR has been supplemented by a great number MDCG documents (>80 documents including >1500 pages), providing interpretations and specifications as well as guidance for implementation of the basic text of MDR. These documents have played a crucial role in aiding all stakeholders in comprehending and consistently implementing the requirements. Additionally, MDR has been updated by two corrigenda and two amending regulations, that have modified the timelines of transition.

The implementation of such a vast array of documents poses significant challenges to notified bodies and manufacturers. The sheer volume of these guidelines necessitates an extensive allocation of resources to assess all documents and translate them into internal processes.
Additionally, crucial guidance documents have become available very late or are still missing. Moreover, some published MDCG documents are not fully applied (e.g. guidance on medicinal consultations not really put into practice by some pharma authorities). Notified bodies need a stable regulatory environment to dedicate all their resources to the MDR transition.

4.4.3. Shorter timelines for notified body designation

The timelines for the designation of notified bodies under the MDR, surpassing 800 days in some cases *(European Commission 2023b, p.1),* limits the overall capacity to conduct certification and conformity assessment. The designation process for new notified bodies needs to be expedited. By increasing the number of designated notified bodies, the overall capacity for certification can be enhanced.

4.4.4. Alternative means of demonstrating competencies

In order to facilitate the expansion of notified body capacity, it is crucial to explore alternative means to demonstrate their staff's competences.
Notified bodies have been required to undergo rigorous evaluations to demonstrate their technical competence and expertise in specific areas of medical device regulation. While this approach ensures a high level of scrutiny and proficiency, it can also lead to resource constraints and potential bottlenecks in the designation process. By allowing alternative means of demonstrating competences, such as recognizing relevant experience and past performance, notified bodies can expand their capacity, without compromising on the quality of assessment.
In a rapidly evolving industry, medical device manufacturers are continuously developing innovative products, some of which may fall outside the current scope of notified body designation. By establishing a streamlined and transparent process for extending the designation scope, notified bodies can adapt to technological advancements promptly and effectively, thereby fostering innovation in the medical device sector.

4.4.5. Facilitate and support the harmonisation efforts of notified bodies

Notified bodies have already started to take measures to harmonize procedures and enhance predictability across all notified bodies.
Currently, these efforts are almost exclusively undertaken by notified bodies themselves through extensive coordination work in NBCG-Med and TEAM-NB, including notified bodies training other notified bodies. Supporting this work by providing a technical secretariat coordinating the crucial harmonisation work of NBCG-Med would truly foster further progress in this area.

4.4.6. Complete and timely applications from manufacturers

As elaborated above, for notified bodies to be able to effectively use their resources and successfully certify medical devices under MDR, it is crucial that manufacturers submit their complete applications in a timely manner. To facilitate this, notified bodies have published a best practice guide on MDR technical documentation in summer 2022. Additionally, regulatory authorities can play a crucial role in facilitating early submission by providing clear, timely and concise guidance.
Notified bodies are deeply concerned as they see the numbers of MDR applications drop and response time by manufacturers, to the raised non-conformities during assessment, increase since the end of 2022, when first drafts of the amending regulation were circulated. Notified bodies are calling on all manufacturers to liaise with their notified bodies at their earliest convenience and to submit all their

applications now to successfully manage this transition together. This would enable the notified bodies to plan accordingly and to spread their resources as evenly as possible over the complete available time. Only successful cooperation between manufacturers and notified bodies can avoid challenging peaks in workload towards the end of the new deadlines.

4.4.7. Availability of experts fulfilling the new requirements

The implementation of the MDR has resulted in a substantial increase in the demand for regulatory affairs experts and professionals with medical device technology expertise. Recruiting sufficiently experienced staff in clinical, regulatory and technical areas has proven difficult as notified bodies face major competition in the labour market from manufacturers, consultancies and regulators. Incoming notified body staff, although they have to fulfil already extensive legal requirements, needs to undergo substantial training programs to comply with the requirements of a granular authorisation system. This leads to very long authorisation timelines and consumes valuable hours of experienced staff in providing training.
Resources needed for training have been intensified by the constant stream of new guidance documents, for which also existing notified body staff has to be trained.
A starting point to free up notified body capacity could be a reassessment of authorisation requirements for notified body personnel, in the light of the experience gained from the application of the MDR.

5. Conclusion

The Regulation (EU) 2023/607 adopted in March 2023, has amended the transitional provisions for certain medical devices covered by the Medical Device Regulation (EU) 2017/745 (MDR). This step has become necessary as the transition process from the former directives MDD/AIMDD could not be completed before the end of the original deadlines. This could have led to a serious threat of a shortage of medical devices on the European market. However, the extension of the deadlines alone will not solve the underlying root causes of the slow transition process.

Notified bodies have been criticized to be insufficiently equipped to fulfil their new regulatory requirements and to not be able to transition the remaining medical device certificates under the directive into the MDR. Notified bodies do not find this to be a justified criticism, as they have taken substantial measures to boost their resources and capacities to meet the increased demands and requirements MDR imposes on them. Notified bodies have invested in hiring additional staff and training both new and existing personnel. They have also enhanced their internal processes, expertise, and infrastructure to align with the new regulatory framework.

Considering the substantial investment and preparations made by notified bodies to accommodate the transition, it is crucial for manufacturers to promptly utilize the available capacity by submitting their applications. This would expedite the transition to the new MDR regime. Additionally, regulatory authorities can play a crucial role in facilitating early submission by providing clear, timely and concise guidance.
Timely and effective coordination between all stakeholders is paramount to prevent the challenges posed by potential peaks in demand for notified body capacity around the new deadlines set by the amending regulation (application submission in 2024, finalisation of certification processes in 2027/2028).

Notified bodies consider that the amended timelines could imply great benefits for the European patients, as they could ensure continued availability of essential medical devices in the European market. However, in order to materialize these benefits, coordinated actions of authorities,

manufacturers and notified bodies are necessary. Notified bodies are fully committed to play their part in making this work.

6. Sources

European Commission (2023a). *Guidance - MDCG endorsed documents and other guidance.* Available at: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en (Accessed: 25 July 2023).
European Commission (2023b). *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.* Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0010. (Accessed: 25 July 2023).

Medical Device Coordination Group (2022*). MDCG 2022-14. MDCG Position Paper Transition to the MDR and IVDR Notified body capacity and availability of medical devices and IVDs***.** Available at: mdcg_2022-14_en.pdf (europa.eu). (Accessed: 25 July 2023).

TEAM-NB (2021a) Team-NB sector survey 2020. [Press Release]. Liège. Available at: https://www.team-nb.org/wp-content/uploads/2021/04/Team-NB-MD-Sector-Survey-PressRelease-20210414.pdf. (Accessed: 25 July 2023).

TEAM-NB (2021b). *Notified Body position paper on MDR/IVDR Implementation.* Liège. Available at: https://www.team-nb.org/wp-content/uploads/2021/12/Team-NB-PositionPaper-on-MDR_IVDR-Implementation-V3.pdf. (Accessed: 25 July 2023).

TEAM-NB (2022a). *Team-NB sector survey 2021.* [Press Release]. Liège. Available at: https://www.team-nb.org/wp-content/uploads/2022/05/Team-NB-MD-Sector-Survey-PressRelease-20220516.pdf. (Accessed: 25 July 2023).

TEAM-NB (2022b). Medical Device Survey 2021. Liège. https://www.team-nb.org/wp-content/uploads/2022/05/Survey-2021-20220516-1.pdf. (Accessed: 25 July 2023).

TEAM-NB (2023). *Team-NB sector survey 2022.* [Press Release]. Liège. Available at: https://www.team-nb.org/wp-content/uploads/members/M2023/Team-NB-MD-Sector-Survey-PressRelease-20230411.pdf. (Accessed: 25 July 2023).

7. Glossary

AIMDD	"Active Implantable Medical Device Directive" Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
Amending Regulation	Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.
MDCG 2022-14	MDCG Position Paper: "Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs" published August 2022
MDCG documents/guidance	Documents endorsed by the Medical Device Coordination Group (MDCG). These documents present a common understanding of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation.
MDD	"Medical Device Directive" Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
MDR	"Medical Device Regulation" Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)
NBCG-Med	Notified Body Coordination Group
TEAM-NB	European Association for Medical Devices of Notified Bodies

About Team-NB

Team-NB is the European Association for Medical Devices of Notified Bodies, Team-NB is dedicated to ensure a high level of patients' safety and confidence.

Our three main areas of focus, have been and will remain:

- ❖ The promotion of innovation, but innovation that is backed by solid safety and effectiveness data. The certification of manufacturers' products is essential to continue the confidence in Medical Devices and In-Vitro Diagnostic products.
- ❖ Our support to notified bodies, through our detailed and state of the art guidance documents, ensures a consistent standard is achieved by our members throughout Europe.
- ❖ Ultimately, Team-NB works to ensure continuous improvement of products, leading to increased patient access to safe innovative products.

Our main objectives, have been and will remain:

- ✓ To improve communications with the EC Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies
- ✓ To promote high technical and ethical standards in the functioning of Notified Bodies
- ✓ To increase competences in decision making processes
- ✓ To make available to the sector a competent work forces as quickly as possible
- ✓ To protect the legal and commercial interests of Notified Bodies in their vital role in the functioning of the three medical device directives.

Team-NB set up **Mirror MDCG-working groups** to allow the members the opportunity to support development of European guidance and enable comments on draft documents in order to coordinate and consolidate input.

Team-NB also set up **task forces** to address specific items in order to harmonise views and come with best practice guides. Today there are 25 tasks forces working on topics such as article 117, classification interpretation, cybersecurity, Lifetime,…

Moreover, the **Team-NB academy** organised several trainings related to the new MDR/IVDR with the aim to help notified bodies deal with new requirements in their assessments. Another purpose is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favoured during the presentations and the cases studies sessions.
Moreover, **Experts session for harmonisation** has been set up at the senior experts' level to share their experience on burning evaluation topics. The objective is that attendees cascade the info into their organisation to reach all reviewers.

In case of any further clarification needed, please contact schlemmer@team-nb.org