Proposed amendments:

https://health.ec.europa.eu/document/download/25e7ea7c-cab3-40cf-86d9-d11f5e7744d8_en?filename=md_com_2025-1023_act_en.pdf

1- Validity of certificates and recertification (MDR: Article 15, IVDR: Article 15)

“The maximum period of validity of certificates (currently 5 years) is removed. Instead of recertifying devices, notified bodies will carry out periodic reviews proportionate to the risk of the device while the certificate is valid.”

Explanation:

Under the existing MDR, certificates have a mandatory expiration date, typically every 5 years, requiring a costly and bureaucratic recertification process to keep products on the market.

The fixed 5-year validity limit is removed. Certificates will no longer have an expiration date. Instead of the traditional recertification process, Notified Bodies will perform **"periodic reviews"** that are proportionate to the risk of the device. As long as the device remains safe and compliant during these reviews, the certificate remains valid indefinitely.

The proposal indicates that, reviews will be "proportionate to the risk." Since "proportionate" is a subjective term, it allows for inconsistent interpretations among Notified Bodies. For instance, one body might mandate a comprehensive review every 12 months, whereas another may deem 24 months sufficient. This lack of uniformity creates regulatory uncertainty.

In a periodic review system, if a Notified Body finds a minor non-compliance during a routine check, they could suspend or restrict the certificate immediately because there is no expiration window to work within. This could lead to sudden supply chain interruptions.

Last but not least, the proposal indicates that Article 56 of the MDR is amended as follows:

“The validity of certificates shall not be limited in time, **unless in exceptional cases where the notified body considers it necessary to limit the period of validity** based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment

performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid. ”

This provision appears to create a 'backdoor' that undermines the proposal for indefinite certificate validity. The term 'exceptional cases' lacks a clear definition and scope, granting Notified Bodies broad discretionary power to impose expiration dates. This ambiguity is likely to exacerbate the existing issue of 'regulatory divergence' between Notified Bodies. Instead of resolving the bureaucratic hurdles, this amendment risks reintroducing them under a different guise. Therefore, the exception should not become the rule. To ensure a level playing field, the Commission should provide a restrictive and exhaustive list of exceptional cases where a certificate’s validity may be limited. Without such a list, the principle of 'indefinite validity' risks being compromised by subjective interpretations.

2- Clinical evidence, non-clinical data and clinical data (MDR: Article 2, point 48, Article 61, Annex II, Annex XIV , IVDR: Annex XIII)

“A wider range of data may qualify as clinical data. The conditions for relying on clinical data of an equivalent device are made more flexible. In Article 61 MDR, the possibility to demonstrate a device’s safety and performance based on non-clinical data alone is expanded. The use of ‘New Approach Methodologies’, such as in silico testing, is promoted. ”

Explanation:

Under the current MDR rules, it was difficult for a manufacturer to get approval by comparing their product to an existing one. They were often forced to conduct their own expensive and repetitive clinical trials. The new proposal changes this by making **Equivalence Rules** much more flexible.

Article 61: The conditions for relying on clinical data of an equivalent device are made more flexible, in particular by removing the requirement for a contract between the two manufacturers...

Manufacturers can now **rely on the clinical data of a "predicate device" (a similar, proven product already on the market)** more easily. SMEs can now keep their products on the market without the burden of new clinical trials for every single component. If the

device is proven to be "equivalent," the manufacturer will not have to conduct years of new clinical trials on thousands of patients. They can present the competitor's decades of accumulated successful results as "proof". A manufacturer can obtain approval by "relying" on someone else's clinical data, but only on the condition that they can prove in a laboratory that their own product is "technically identical" to that device.

It helps avoid price increases **by lowering the disproportionate certification costs** applied to simple instruments. It also reduces the risk that essential but low-margin products are withdrawn from the market. In addition, incremental improvements to existing designs can be made available to healthcare professionals more quickly, as baseline safety has already been demonstrated through equivalence.

However, while the proposed flexibility in equivalence rules (Article 61 MDR) is a significant step towards reducing the administrative burden for SMEs, the lack of precise definitions for terms such as 'similar materials' and 'technical equivalence' remains a major concern. As seen in previous MDR implementations, subjective terminology triggers diverging interpretations by Notified Bodies. This inconsistency directly contradicts the Commission's objective to ensure a 'predictable and sustainable regulatory framework'.

From a dental sector perspective, these changes are particularly important, as many dental devices are based on existing designs with incremental modifications. Clear and consistent equivalence criteria would help ensure continued availability of essential dental products, avoid unnecessary cost increases, and support timely access for dental professionals and patients.

Finally, standardizing these criteria would be a crucial step toward ensuring that the increased flexibility truly benefits the industry while maintaining the necessary legal certainty and a level playing field.

3- Well-established technologies (MDR: Article 2, point 72, Article 18, Article 32, Article 52, Article 61, Article 86)

“A definition of ‘well-established technology device’ is introduced for devices which will be subject to more proportionate requirements, replacing the lists of devices in the current Articles 18(3), 52(4) and 61(6)(b) MDR.”

Explanation:

According to the MDR revision proposal, there are three main pillars to determine if a device qualifies as WET:

1. Official Commission Lists: The European Commission may publish **official lists** specifying which categories of devices are considered WET. If a product group is on this list, it is automatically granted WET status. (Article 3 - Amendment and Implementation of Certain Definitions)

2. Three Core Legal Criteria: For devices not yet on the list, the following criteria must be met:

- Long-standing Market History: The device or its equivalents must have been **safely on the market for a significant period**.
- Common Clinical Practice: The device must be a "**standard of care**", rather than being a novel or experimental technology. (simple, common and stable design)
- Clean Safety Record: There must be **no history of serious safety signals** or design-related recalls associated with the device.

3. Technical Documentation and Notified Body Validation: The **manufacturer must demonstrate** that the device meets WET criteria within its Technical File. The Notified Body will review this evidence and make the final decision on whether the device can benefit from the simplified WET requirements.

The proposal introduces a significant simplification to the MDR by establishing a formal definition for "well-established technology device. "

This change aims to reduce the complexity of the current MDR framework and ensure that "proportionate" requirements (less costly and less bureaucratic) are applied to specific device groups.

Here are the key innovations and benefits introduced by this definition:

1) **Implant Card Exemptions (Article 18):** The current MDR Article 18(3) lists specific devices (such as sutures, staples, dental fillings, etc.) that are exempt from the implant card requirement. The new regulation removes this specific list and replaces it with a direct reference to "well-established technology devices," thereby future-proofing and simplifying the exemption criteria.

2) **Clinical Evaluation and Data Requirements (Article 61):** The specific list of devices in Article 61(6)(b) (such as sutures, staples, dental fillings, etc.) that are exempt from certain clinical data requirements is replaced by this new definition. For these devices, equivalence rules can be applied more flexibly, alleviating the

burden on manufacturers to conduct extensive new clinical investigations for well-understood technologies.

3) **Conformity Assessment Procedures (Article 52):** In the same way, for conformity assessment procedures, a general category of well-established technology devices has been created to replace the specific list of items like sutures, staples, dental fillings, and others previously exempted in the regulation.

4) **Summary of Safety and Clinical Performance (SSCP - Article 32):** The scope of data required in SSCP reports for these WET devices will be more streamlined, reflecting their low-risk and well-known nature.

5) **Periodic Safety Update Reports (PSUR - Article 86):** The frequency or level of detail for reporting for this WET category of devices has been rearranged according to a risk-based approach, significantly reducing the administrative burden on manufacturers.

However, as seen in the previous proposals, the definition of Well-Established Technology (WET) faces the same issue of ambiguity. Terms like 'simple,' 'common,' and 'stable design' are too subjective and lack clear boundaries. This vagueness will lead to different interpretations by Notified Bodies, creating the very unpredictability intended to be avoided. To truly reduce the administrative burden, the Commission should provide a clear positive list of WET devices or set measurable criteria instead of using vague descriptions.

4- Classification rules (MDR: Annex VIII)

“Some classification rules are adapted resulting in lower risk classes for certain devices, such as reusable surgical instruments, accessories to active implantable devices and software.”

Explanation:

Current Regulation (MDR Annex VIII, Rule 6): Under the current MDR, reusable surgical instruments are classified as **Class Ir**. However, the main challenge is that their classification depends on the specific body part they contact and the duration of use. For "transient use" (less than 60 minutes), they are generally Class I/Ir. But for "short-term

use" (60 minutes to 30 days), if the instrument is used in a more invasive procedure or near the central circulatory/nervous system, the classification jumps to **Class IIa or even IIb**.

The Proposed Amendment (Annex VIII, Section 5.2 and 5.3): The new amendment simplifies this significantly. According to sections (c) and (d), these devices are now defined as: “reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as **Class I**.” (Note: Class Ir is not a risk class, but rather a subcategory of Class I)

In conclusion, the new amendment eliminates the ambiguity by stating, "No matter which part of the body it touches, it is Class I." This effectively reduces the administrative burden by preventing these instruments from falling into higher risk classes (IIa/IIb), thereby limiting the Notified Body's involvement to only the reuse/sterilization aspects rather than a full clinical and technical file assessment.

For dental professionals, this amendment is a critical development that ensures the continued availability of essential clinical tools. Under the current rules, standard instruments could be 'up-classified' to high-risk categories (Class IIa or IIb) depending on the surgical site or the duration of the procedure. This new amendment eliminates that complexity by fixing these reusable instruments as Class I, regardless of where they are used in the mouth. For practitioners, this means lower procurement costs and uninterrupted access to a wide variety of specialized surgical tools, as manufacturers are no longer forced to withdraw products due to the overwhelming clinical data requirements of higher risk classes.

5- Reprocessing of single-use devices (MDR: Article 17)

“Manufacturers will be obliged to provide a justification for a ‘single-use’ claim. All devices that are not intended for single-use can be reprocessed in accordance with the instructions provided by the manufacturer. A person who fully refurbishes a single-use device will be the manufacturer of the fully refurbished device. The provision will become applicable five years after entry into force. ”

Explanation:

This amendment challenges the "disposable culture" in healthcare by demanding more accountability from manufacturers. Manufacturers can no longer arbitrarily label a device as "single-use." They must provide a valid scientific or safety justification for why the device cannot be reused. If a device is not proven to be strictly single-use, the

manufacturer is obligated to provide clear reprocessing instructions so healthcare providers can safely reuse it. **Entities that fully refurbish single-use devices will be legally recognized as the "manufacturer," taking full responsibility for the safety of the renovated product.** To allow the industry to adapt, this provision will become applicable **five years** after the regulation enters into force.

6- Conformity assessment procedures (MDR: Article 52, Annexes IX, X, XI, IVDR: Article 48, Annexes IX, X, XI)

“The involvement of notified bodies in the conformity assessment of lower and medium risk devices (class IIa and IIb and class B and C) will be reduced (technical documentation assessment of one representative device for a generic device group, for a category or for the entire portfolio). No systematic technical documentation assessment of representative devices will be required during surveillance activities. Class A sterile IVD will not require notified body involvement. Notified bodies will have the possibility to replace on-site audits by remote audits. Where justified due to absence of safety issues, surveillance audits should be conducted only every two years. Unannounced audits should be conducted ‘for-cause’. Reduced timelines for consultation of medicinal products and SoHO authorities. ”

Explanation:

The amendment addresses the "disproportionate burden" placed on lower and medium-risk devices (Class IIa, IIb, and Class B/C IVDs). Instead of assessing every single device, Notified Bodies will now assess **one representative device** for a generic category or an entire portfolio. It introduces the possibility of **remote audits** and extends the interval of surveillance audits to **every two years** for devices with a clean safety record. Unannounced audits will shift from being random to being "for-cause", and no systematic technical file review will be required during routine surveillance.

In conclusion, this risk-based approach ensures that Notified Bodies can focus their limited resources on truly high-risk devices while **allowing standard medical devices to remain on the market more easily and affordably.**