EUROMCONTACT
THE EUROPEAN ASSOCIATION OF THE
CONTACT LENS AND LENS CARE INDUSTRY

# European Commission's proposal on simplifying and reducing the burden of the rules on medical devices

Position paper

May 2026

**Table of contents**



## The time for targeted MDR reform: translating broad consensus into action to restore proportionality and efficiency of the system for all

On 16 December 2025, the European Commission proposed a targeted revision of the Regulation (EU) 2017/745 on medical devices (MDR) with the objective of addressing key challenges identified during the implementation of the current framework. The proposal aims to improve the proportionality, efficiency, and predictability of the system in order to ensure continued patient access to safe and innovative medical devices across the Union, while ensuring a very high level of patient safety.

**The need for reform has been widely recognised** by EU institutions, Member States, healthcare professionals, and industry alike. On 23 October 2024, the European Parliament adopted a Resolution calling for an urgent revision of the MDR, notably to improve predictability and reduce unnecessary administrative burdens. Shortly thereafter, on 3 December 2024, nine Member

States presented a joint note during the EPSCO Council highlighting the need for reforms aimed at reducing administrative obligations of stakeholders.

In response to the significant implementation challenges associated with the MDR, the European Commission launched a targeted evaluation of the framework in 2025. **The evaluation identified several structural shortcomings affecting the efficiency, predictability, and proportionality of the system, with direct consequences for innovation, device availability, healthcare delivery, and patient access across the Union**.

In particular, the evaluation highlighted:

- a fragmented regulatory framework leading to inefficiencies and unnecessary burdens for stakeholders;
- redundant reporting requirements and duplication of assessments, resulting in substantial and unforeseen administrative burdens;
- insufficient predictability and disproportionate regulatory requirements in certain areas of the system.

The findings of the evaluation were further reflected in the accompanying Staff Working Document (SWD(2025)1051), which noted that :

- 70% of respondents, across all groups, referenced market withdrawal of devices due to high compliance costs, lengthy certification processes, and limited NB capacity
- **almost 60% of HCP/HCP associations reported that in the last 3 years they experienced problems purchasing/being supplied with relevant devices**

The Commission proposal therefore responds to repeated calls from the European Parliament, Member States, and stakeholders to simplify the regulatory framework and improve the availability of medical devices within the Union. **As recognised in the evaluation accompanying the proposal, the increased administrative burden resulting from the Regulation could be addressed by streamlining reporting obligations as well as avoiding duplication and overlapping of reports and their assessment.**

EuromContact shares the view that, while the MDR has introduced important improvements in terms of traceability, transparency, and patient safety, its implementation has also generated disproportionate documentation and reporting obligations, particularly for legacy devices with long-standing safety records, without generating corresponding additional safety benefits.

During the 2025 public consultation, EuromContact therefore called for concrete measures to ensure:

- for all classes of devices, a truly risk-based approach that ensures proportionality for devices with long-established safety records;

- a stronger focus on patient safety and quality rather than excessive administrative formalities;
- clarification of the requirements for better harmonization in MDR implementation.

**EuromContact generally welcomes the European Commission's proposal and supports its swift adoption**, **while we recommend a number of targeted and technical clarifications** and limited additional improvements to address remaining shortcomings in the MDR framework, in order to fully achieve the intended objectives of regulatory efficiency, consistency, proportionality while strengthening the EU's attractiveness for innovative technologies.

## 1. Conformity assessment and certification

The MDR significantly reinforced conformity assessment requirements for medical devices by introducing stricter clinical evaluation obligations and expanded technical documentation requirements. **While these measures were intended to strengthen patient safety, their implementation has often resulted in disproportionate administrative burdens for stable, long-established devices with extensive market surveillance records proving their safety.**

Despite the MDR's stated objective of proportionality, Class IIa and Class IIb devices are frequently subject to scrutiny levels comparable to those applied to high-risk or novel devices. The depth of quality management system (QMS) assessments and technical documentation reviews is not adjusted to the risk classification. As a result, **devices that have been safely used for decades are assessed as if they were high-risk or novel technologies**, generating excessive documentation obligations without corresponding additional safety benefits. A more proportionate and risk-based approach would allow notified bodies and competent authorities to **focus resources where they are most needed and where they can provide the greatest added value for patient safety.**

For contact lenses and lens care products for instance, the MDR currently requires **extensive and repetitive documentation exercises, even where clinical evidence and safety data remain unchanged** over time. In many cases, this formal documentation required does not generate new safety insights, but creates unnecessary administrative burden. This situation has led to a significant increase in compliance costs, particularly for SMEs, and in some cases contributes to market withdrawals for economic reasons rather than safety concerns. According to a 2024 survey conducted by EuromContact, conformity assessment costs increased by 170% under the MDR compared to the previous Medical Devices Directive (MDD) framework.

At the same time, manufacturers continue to face **evolving and inconsistent practices among notified bodies and competent authorities**, resulting in reduced predictability and delays in access to compliant products.

EuromContact welcomes the **revision proposal, which appropriately addresses several key shortcomings** of the current system, including the revision of :

- excessive reliance on formal documentation and repeated testing for stable devices instead of leveraging existing surveillance and market experience data;
- disproportionate administrative formalities that increase costs and delay market access without improving patient safety;
- inconsistent and excessive approaches to sampling plans;
- lack of clarity regarding post-certification modifications, as well as divergent interpretations and practices among notified bodies.

EuromContact therefore strongly **welcomes the proposal's efforts to introduce a more effective risk-based and proportionate approach to conformity assessment and certification.** In particular, EuromContact supports the following proposed measures and calls for their maintenance in the final text :

- **Harmonisation of practices and coordination among notified bodies**

EuromContact strongly **welcomes the measures aimed at improving consistency and harmonisation across notified bodies**.

In particular, we support:

- the establishment of a **more harmonised framework for sampling plans** and procedural aspects related to the selection of the representative device and sample tests through implementing acts;
- the **mechanism allowing unresolved disputes** arising during conformity assessment procedures to be referred to the authority responsible for the notified body;
- the role given to NBCG Med to facilitate harmonisation and common approaches regarding conformity assessment activities, including the **development of common templates**.

Improved coordination and convergence are essential to ensuring consistent interpretation and application of MDR requirements across the Union and to reducing regulatory divergence.

- **Clearer and more predictable rules for change management**

EuromContact strongly **supports the introduction of clearer and more proportionate rules for post-certification modifications of devices and QMS**.

In particular, we welcome:

- the requirement for notified bodies to have **procedures and contractual arrangements** that clearly distinguish between :
  - changes that do not need to be reported,
  - changes that need to be reported without requiring prior approval,
  - and changes that require prior approval.

- the possibility for manufacturers and notified bodies to agree on predetermined change control plans (**PCCP**s) enabling the manufacturer to implement changes in accordance with such a plan without prior information.

Establishing a transparent and standardized process for post-certification modifications would significantly improve predictability and reduce delays in implementing modifications that may benefit patients.

- **Digitalization of conformity assessment procedures**

Euromcontact welcomes the fact that the submission of information or documents in accordance with the MDR shall take place electronically and that manufacturers may draw up and make available in a digital format the technical documentation and any reports or other documents required pursuant to the MDR.

While EuromContact broadly supports the objectives of the revision proposal, **some further adjustments should be considered**:

- **Clarifying the scope of structured dialogue to include clinical strategy**

EuromContact strongly **supports the introduction of a formal framework for structured dialogue between manufacturers and notified bodies** before and after submission of conformity assessment applications. The requirement for notified bodies to establish documented procedures for dialogue with manufacturers would improve predictability of the process.

However, EuromContact **recommends clarifying that the structured dialogue framework includes discussions on clinical strategy and clinical evaluation expectations**. Clinical evidence generation is often critical to overall development timelines and needs to be anticipated. Early clarity on the clinical strategy is essential for manufacturers to plan appropriate evidence generation. In the absence of early alignment with the notified body, manufacturers may face significant delays if additional clinical investigations are required after application, with substantial impact on timelines. Including clinical strategy in both pre- and post-application dialogue would enhance predictability and improve the efficiency of conformity assessment, while maintaining the level of scrutiny required under the MDR.

- **Rolling reviews of technical documentation should become the norm**

EuromContact welcomes the possibility for manufacturers to submit a plan and timeline for technical documentation submission, rather than requiring the complete technical documentation package at the initial application stage.

EuromContact similarly **welcomes the introduction of rolling reviews**, inviting notified bodies to assess documentation progressively as it becomes available. However, the current wording

stating that notified bodies shall perform rolling reviews "where appropriate" introduces unnecessary ambiguity and may lead to inconsistent implementation across notified bodies. This could result in unequal access to more efficient assessment pathways and reduced predictability for manufacturers. Rolling review is a well-established regulatory tool to facilitate earlier engagement and progressive assessment of data as it becomes available. Its systematic use in other jurisdictions has demonstrated benefits in terms of efficiency, resource planning, and timely access to compliant products, without lowering regulatory standards. EuromContact therefore **recommends removing "where appropriate" in order to ensure more harmonised and predictable access to rolling review procedures**.

- **Proportionate and risk-based conformity assessment with clear for-cause triggers**

EuromContact strongly **supports:**

- **the establishment of a more harmonised and proportionate framework for sampling plans,** including the recalibration of assessment requirements for class IIa and IIb devices;
- the requirement that notified bodies apply a risk-based and proportionate approach when selecting representative devices for assessment;
- the **possibility to leverage evidence from previous assessments** when conducting conformity assessment activities.

These measures would improve efficiency, reduce unnecessary duplication, and better align assessment depth with the actual risk profile of devices.

But the proposal introduces the concept of "for-cause" assessments of technical documentation of additional representative devices for class IIa and class IIb devices on "duly justified grounds" identified during the QMS assessment, without defining clearly the circumstances triggering such assessments. The absence of definition might lead to divergent interpretations and inconsistent application across notified bodies and Member States. Establishing a clear definition is necessary to ensure legal certainty and a harmonised understanding of the circumstances under which such assessments are triggered. Aligning this definition with international practices would promote regulatory convergence and provide a clear framework for implementation. We **propose a definition for 'for-cause' assessment** : Assessment triggered by evidence of potential violations, safety issues, or quality problems.

- **A harmonised framework for periodic reviews**

EuromContact strongly **supports replacing fixed certificate validity periods with a system based on proportionate periodic reviews and surveillance activities**. Under the proposal, certificates would no longer be systematically subject to fixed validity periods, unless duly justified by specific factors such as device novelty, risk classification, clinical evaluation outcomes and conclusions from the risk analysis.

This approach is more proportionate and better reflects the lifecycle nature of medical device regulation.

EuromContact also **welcomes the requirement that periodic reviews be proportionate** to the risk class of the device. To ensure consistent implementation across the Union, EuromContact **recommends explicitly requiring that these procedures shall reflect common approaches**, taking into account the coordination activities referred to in Article 49. Differences in how notified bodies perform periodic reviews may lead to inconsistent levels of scrutiny and divergent expectations across the Union. Requiring a harmonised approach to such reviews would improve consistency and predictability for manufacturers. This is particularly important for maintaining a level playing field, supporting the effective functioning of the internal market and avoiding unnecessary regulatory burden or delays, without lowering the level of protection.

- **No listing of manufacturing sites on certificates**

EuromContact **opposes the proposal requiring EU QMS certificates and EU quality assurance certificates to explicitly list manufacturing sites**.

Manufacturing sites are already subject to assessment and oversight by notified bodies as part of the conformity assessment process and are documented within the technical documentation and quality management system. Requiring their explicit listing on certificates leads to frequent certificate updates in the event of changes to manufacturing locations, even where such changes do not affect the conformity of the device. This would result in avoidable administrative workload for both manufacturers and notified bodies without providing additional value in terms of safety or performance and may lead to delays in maintaining valid certification and continuity of supply.

## 2. Clinical Investigation and Evaluation

The MDR significantly strengthened clinical evidence requirements with the objective of enhancing patient safety. While this objective is fully supported by EuromContact, these **requirements are disproportionately burdensome for stable devices with a long history of safe use and substantial post-market experience**. In this regard, EuromContact welcomes the revision proposal's objective of introducing a more proportionate and risk-based approach by focusing the most stringent requirements on higher-risk and novel devices while adapting requirements for lower-risk and long-standing products.

Beyond proportionality concerns, **manufacturers also face lack of clarity, predictability, and harmonization of requirements** : clear criteria to specify and justify the level of clinical evidence required are needed.

EuromContact strongly **welcomes the more proportionate approach introduced by the revision proposal and supports** in particular the following measures :

- **Broader definition of "clinical data"** : including the explicit recognition of other studies published in scientific literature and giving more flexibity to choose among the different sources listed in the MDR better reflects the diversity of evidence sources available for long-standing technologies and supports a lifecycle-based approach to evidence generation.

- **Recognition that non-clinical data may demonstrate safety and performance under certain conditions**. The proposal appropriately maintains robust safeguards, as manufacturers would still be required to provide a duly substantiated justification explaining why confirmation through clinical data is not considered necessary, and notified bodies would remain responsible for assessing the adequacy of that justification.

- **Predictable and harmonised identification of Well Established Technologies (WET)** : Empowering the Commission to establish **lists of devices** that fall within, or outside, the definition of WET without limiting eligibility because of device classification, together with the introduction of a **WET definition** within the MDR framework, are important steps towards greater consistency and predictability. But we consider that **further clarification will be necessary to ensure consistent implementation** in practice, as several concepts remain open to interpretation, such as "associated with safety issues in the past", "long history on the Union market". The future list(s) will therefore play a key role in improving predictability, harmonisation, and consistency across notified bodies and Member States.

**Additional improvements recommended :**

- **Explicit recognition of Real-World Data (RWD)** : EuromContact recommends explicitly including RWD among the acceptable sources of non-clinical evidence, alongside performance evaluation, bench testing**,** in vitro, ex vivo, in silico testing, computational modeling or simulation and pre-clinical evaluation. **RWD should be explicitly mentioned** as a valid source of data in cases where clinical investigations are not deemed appropriate. While RWD is acknowledged in the Commission's fact sheet accompanying the revision proposal, it is not explicitly reflected in the current legal text, leading to uncertainty and potential inconsistencies in interpretation. Clarifying that RWD may be used alongside other non-clinical data is consistent with the MDR's lifecycle approach to evidence generation and current scientific practice. RWD can provide robust information on safety and performance.

- **Inclusion of a definition of Real-World Data**: to ensure legal certainty and harmonised interpretation, EuromContact also recommends introducing a definition of "real-world data" : "*data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources besides clinical investigation".* The introduction of a definition of RWD is necessary to ensure a harmonised understanding and consistent use of this concept across the Regulation, and aligning the Regulation with terminology used

in other jurisdictions and by international fora such as IMDRF, thereby facilitating global regulatory convergence.

## 3. General Safety and Performance Requirement (GSPR)

Compliance with the General Safety and Performance Requirements (GSPRs) is a core obligation under the MDR and applies to all medical devices, irrespective of their classification. **The revision proposal appropriately maintains this fundamental requirement**.

EuromContact supports the objective of ensuring a high level of patient safety and performance through the GSPR framework. At the same time, the implementation of these requirements should remain proportionate, predictable, and aligned with technological and regulatory developments, particularly in the area of digitalisation.

**EuromContact welcomes** several measures introduced by the revision proposal aimed at modernising and clarifying the GSPR framework :

- **Clearer and more flexible approach to equivalence** : the proposal appropriately clarifies that the equivalence criteria is based on similarity rather than identical design. Today, manufacturers face **inconsistent approach** across NBs regarding the concept of "equivalence", many NBs insisting that equivalence requires an identical device, making it **nearly impossible to claim equivalence in practice** because manufacturers cannot demonstrate that the device of a competitor is identical, since they do not have access to the detailed technical documentation of competitors' devices. As a result, **manufacturers must demonstrate identical technical, biological, and clinical characteristics through extensive studies and repeat the same tests** for devices produced using the same monomer mixtures across manufacturers, with established safety profiles, despite substantial post-market surveillance data. For stable, long-established materials and low risk devices like contact lenses, this approach, especially on biocompatibility testing requirements, is disproportionate. **FDA criteria are more flexible in defining equivalence**, allowing manufacturers to rely partly on evidence from a "predicate" or equivalent device.
- **Digital labeling :** allowing labels to be provided in digital form, under conditions to be specified through implementing acts, would represent an important step towards the modernisation and digitalisation of the regulatory framework. Digital labelling may improve access to up-to-date information, facilitate multilingual information management, reduce environmental impact, support more efficient supply chain management and improve usability for healthcare professionals and patients.

While EuromContact broadly supports the objectives of the revision proposal, **some further adjustments should be considered**:

- **Need for appropriate transition periods for amendments to GSPRs** : The revision proposal would empower the European Commission to adopt delegated acts amending the GSPRs. Such delegated acts may introduce technical or substantive changes that require updates to processes, documentation, or compliance workflows. In particular, changes to GSPRs can affect design, risk management, and technical documentation, making immediate application impractical. EuromContact recommends that any delegated act amending the GSPRs should include an appropriate transition period allowing sufficient time for implementation.

- **Electronic Instructions for Use (e-IFU) for lay users** : The current restriction of eIFU to professional users is no longer appropriate in a digital healthcare environment. **Electronic instructions should be possible for lay users under appropriate usability and accessibility safeguards**, **preserving the right to receive paper instructions on request**. Class I and Class IIa devices are characterized by lower risk and often simple operation. Allowing electronic instructions for use at least for these devices would facilitate a more flexible and efficient redistribution of devices in the event of supply disruptions, reduce the environmental impact associated with paper leaflets and align with existing EU digitalisation policies, while ensuring access to the most up-to-date information and improving readability for users. In a survey conducted by OpinionWay among 1008 contact lens wearers across the 27 EU Member States, **85% of respondents indicated that they prefer to have instructions for use of their contact lenses and lens care product in digital format with option to request a paper version**, rather than a paper leaflet[1]. 98% of respondents reported seeing benefits in digital instructions for use. The most frequently cited advantages were “Access to the information at all time and everywhere” (64%) and “Easier access to the information” (58%).

  EuromContact proposes adding **in annex I that where instructions for use are provided for Class I and Class IIa devices, they may be supplied in non-paper format** (e.g. electronic). Appropriate safeguards, including the availability of paper copies upon request as already required by the MDR, are fully maintained.

## 4. Post-Market Surveillance and Vigilance

Post-market surveillance (PMS) is one of the major improvements introduced by the MDR compared to the previous MDD framework. By strengthening lifecycle monitoring and vigilance

[1] OpinionWay for EuromContact, Survey among contact lens wearer in the European Union, November 2023

obligations, the MDR established a more robust and systematic approach to the continuous evaluation of device safety and performance after market placement. EuromContact fully supports the objectives of the PMS and vigilance framework and recognises the important role of post-market data and clinical feedback in improving product quality, updating technical documentation, and ensuring continuous patient safety.

**But in practice, the current PMS and vigilance requirements have proven disproportionate for stable, lower-risk devices** such as contact lenses and lens care products. Despite MDR Article 83(1) explicitly requiring PMS systems to be proportionate to the risk class, many low- and medium-risk devices are effectively subject to requirements comparable to those applied to Class III devices. This has resulted in **excessive documentation, redundant reporting and overlapping PMSV processes without corresponding additional patient safety benefits**, especially for lower-risk and long-established devices :

- Duplication across PMS documents (PMCF Plan, PMCF Report, PSUR, PMS Plan)
- Frequent and inconsistently defined PMS document updates, especially PMCF
- Short and multiple vigilance reporting timelines compared to other jurisdictions (2/10/15 days versus 30 days)
- Redundant reviews of vigilance reports by notified bodies despite vigilance oversight primarily falling within the competence of national competent authorities
- Additional fees, administrative complexity, and inconsistencies resulting from duplicate notified body review processes

This excessive administrative workload diverts resources away from higher-value post-market surveillance activities and may ultimately reduce the efficiency of the overall system. A more proportionate and risk-based approach is necessary, **focusing on the quality and relevance of information rather than the quantity** of documentation produced.

EuromContact strongly **welcomes the revision proposal's efforts to introduce greater proportionality into PMS requirements, particularly for lower-risk devices.** Without undermining the important added value introduced by the MDR, the revision proposal appropriately seeks to :

- reduce unnecessary reporting obligations for lower risk devices;
- focus regulatory resources on higher-risk devices;
- prioritise meaningful safety information over formal documentation volume.

In particular, EuromContact strongly **supports the following proposed measures** :

- **More proportionate PSUR requirements** : the reduction of Periodic Safety Update Report (PSUR) mandatory update frequency for class IIb and IIa, while maintaining the obligation to update PSUR when necessary / when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects, maintains an

appropriate level of oversight while reducing unnecessary administrative burden for stable devices.

- **Removal of the separate "PMCF evaluation report"**, results of the analysis of the findings of the post-market clinical follow-up (PMCF) being documented in the clinical evaluation report and the technical documentation.

- **Extension of vigilance reporting timelines** : extending the maximum deadline for reporting serious incidents from 15 days to 30 days would better align Union requirements with international practices, while still ensuring that reports are submitted without undue delay. Longer reporting timelines would improve the quality and completeness of submitted information.

- **More proportionate and risk-based surveillance activities** : short-notice or unannounced audits performed when justified by concerns arising from PMS or vigilance data or at the request of a competent authority, annual surveillance audits conducted where justified in light of the results of previous surveillance audits and assessments, and surveillance audits every 24 months in the absence of identified concerns would allow notified bodies and competent authorities to focus resources and oversight activities where risks or safety concerns genuinely justify increased scrutiny.

While EuromContact **supports the risk-based approach introduced by the revision proposal, moving from systematic technical documentation assessments during surveillance to targeted assessments of representative devices only where notified bodies identify potential concerns based on PMS data or other duly justified grounds for Class IIa and Class IIb devices,** the proposal unfortunately does not define the concept of "for-cause assessment". The absence of clear definition may lead to divergent interpretations and inconsistent application across notified bodies and Member States. EuromContact **recommend establishing a clear definition** to ensure legal certainty and a harmonised understanding of the circumstances under which such assessments are triggered. Aligning this definition with international practices would promote regulatory convergence and provide a clear framework for implementation. We propose a definition : *'for-cause' assessment : Assessment triggered by evidence of potential violations, safety issues, or quality problems.*

## 5. Identification and traceability of devices

**The MDR significantly strengthened traceability and transparency requirements for medical devices** compared to the previous MDD. Key requirements introduced under the MDR include:

- implementation of the Unique Device Identification (UDI) System, including the Master UDI for highly individualised devices;

- additional labelling obligations;

- registration of economic operators, devices and certificates in EUDAMED.

**The revision proposal appropriately maintains these core requirements**, which remain essential to ensuring traceability, transparency, and trust in the system.

In addition, **EuromContact welcomes the proposal providing that the relevant information available in EUDAMED shall be retrieved directly from EUDAMED by Member States maintaining national databases.** This approach will significantly reduce duplication of work while ensuring a single, harmonised source of information for patients, healthcare professionals, competent authorities and economic operators.

At the same time, while industry has already undertaken substantial efforts and investments to comply with the extensive traceability and registration obligations introduced under the MDR, certain additional requirements proposed in the revision risk creating unnecessary administrative burden without providing corresponding benefits in terms of patient safety, transparency, or regulatory efficiency. **The following aspects should therefore be reconsidered.**

- **Keeping MD symbol for accessories and annex XVI products**

EuromContact opposes the proposed removal of the "MD" symbol for accessories to medical devices and products covered by Annex XVI, such as colored contact lenses. Excluding accessories and Annex XVI products from the MD symbol would represent a deviation from current practice, where such products may already bear the "MD" symbol in application of the MDR, and therefore trigger new labeling updates including for products that are already MDR compliant. The indication that the device is a medical device indicates that the device meets all the MDR requirements, which is a key information for patients and healthcare professionals. **We therefore recommend maintaining the possibility for the "MD" symbol to apply to medical devices, accessories for medical devices, Annex XVI products and accessories to Annex XVI products**.

- **Ensuring effective adoption of harmonised and digital Certificates of Free Sale**

EuromContact welcomes the proposal empowering the Commission to adopt implementing acts developing a harmonised template for certificates of free sale. Such a template would significantly improve consistency, legal certainty, and predictability for manufacturers across the Union. Given the importance of this measure for exports to third countries, EuromContact recommends strengthening the provision by replacing "may" with "shall", thereby **ensuring that the implementing acts are effectively adopted**.

In addition, preferably issued electronically, the **harmonised template should explicitly allow:**

- **the use of digital signatures;**
- **where applicable, the use of an electronic apostille or legalization**.

Enabling the use of digital signatures aligns with international and EU practices for the digitalisation of official documents and supports the broader digitalisation objectives promoted by the MDR revision proposal. Recognising the use of an apostille, where applicable, ensures that

certificates remain valid and easily accepted in third countries under international agreements. This approach would facilitate a more efficient, secure, and internationally recognised process for issuing certificates of free sale, while maintaining full regulatory oversight and the level of health protection required under the MDR.

- **Confidentiality safeguards for Certificates of Free Sale published in EUDAMED**

Should competent authorities make certificates of free sale publicly available in EUDAMED, as envisaged under the proposal, EuromContact considers that these **certificates shall not include information identifying third countries** in which the device is or may be placed on the market, exported, or made available. The primary purpose of certificates of free sale is to confirm that a device is CE-marked and legally marketed within the Union for export purposes. They should not disclose commercially sensitive information relating to manufacturers' export activities or commercial strategies. Appropriate safeguards should therefore be introduced to ensure the protection of confidential commercial information in a highly competitive international environment.

## 6. Obligations of economic operators

EuromContact welcomes certain targeted clarifications introduced by the revision proposal regarding the obligations of economic operators, while considering that some proposed changes should be reconsidered and that additional proportionate improvements should be introduced.

- **Clarification of the scope of Article 10a obligations** : EuromContact strongly welcomes the provision requiring the European Medicines Agency (EMA) to publish a list of devices or categories of devices to which Article 10a applies. The scope of this obligation has so far remained insufficiently clear, leading many manufacturers to adapt and implement complex monitoring and reporting processes despite the fact that Article 10a should only apply to devices for which an interruption or discontinuation of supply could reasonably be expected to result in serious harm or a risk of serious harm to patients or public health. **Providing a clearly identified scope through an EMA list would therefore significantly improve legal certainty and predictability**, while ensuring that supply monitoring obligations remain focused on genuinely critical devices.

- **Maintain manufacturer notification for relabelled and repackaged devices**: EuromContact strongly **disagrees with the proposed removal of the obligation for distributors and importers to inform manufacturers** prior to placing relabelled or repackaged devices on the market. The proposed deletion would remove an important safeguard. Manufacturers remain ultimately responsible for the safety and performance of their devices. Maintaining the requirement to inform the manufacturer, and to provide a sample or mock-up of the relabelled or repackaged device, is essential to support the

manufacturer's role and to enable verification, where necessary. Restoring this requirement would strengthen patient safety, support effective post-market oversight, and ensure that responsibilities across economic operators remain coherent, without imposing disproportionate burden.

- **Introduction of proportionate sampling methods for importers** : Euromcontact proposes to allow importers to apply a sampling method that is representative of the devices they supplied in order to meet the requirements set in article 13. Verifying every individual device is often impractical for importers, particularly when IFUs or labelling are enclosed within sealed packaging. While sampling is currently permitted for distributors, it is not explicitly allowed for importers. Allowing importers to apply a representative sampling method as well would ensure compliance in a practical, proportionate, and risk-based manner, while preserving the ability to detect non-conformities.

## 7. International cooperation

The proposed "International Cooperation" chapter is an important and welcome addition to the MDR framework. In particular, EuromContact **supports full EU participation in the Medical Device Single Audit Program (MDSAP), including the recognition of MDSAP certificates** for CE marking purposes, as this would enhance regulatory efficiency, reduce unnecessary duplication, and strengthen the attractiveness and global competitiveness of the EU market.

## ABOUT EUROMCONTACT

*EUROMCONTACT is the European trade association representing manufacturers of contact lenses and lens care products, which are medical devices. Our members represent 90% of the soft contact lens and 80% of the contact lens products markets in the EU.*