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

Contribution to the targeted evaluation of the EU Medical Devices Regulation (MDR)

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SUMMARY

The EU Medical Devices Regulation (MDR) aims to create a robust legal framework that ensures only safe and effective devices are available on the EU market, to protect patient safety and public health while supporting innovation. EuromContact fully supports these goals and, 8 years after its publication, takes this opportunity to assess the MDR's effectiveness, efficiency, relevance, coherence, and added value.

Representing manufacturers of contact lenses and lens care products, the contribution focuses on the impact of the MDR on class IIa and class IIb medical devices and on annex XVI products. **While the MDR has introduced significant benefits, such as a more structured regulatory system, reduced ambiguity, and improved consistency across the EU, it has also imposed substantial documentation and reporting burdens, particularly for legacy devices with long-standing safety records, without adding clear patient safety benefits for these devices.** Many low-risk, well-established devices face the same stringent requirements as high-risk, novel devices, leading to disproportionate complexity. In these cases, the bureaucratic weight of MDR threatens the viability of some medical devices, especially for SMEs.

Despite MDR's numerous references to a risk-based approach, its implementation fails to adequately distinguish between high-risk new technologies and stable, low-risk devices. While some positive developments, such as a focus on quality management systems (QMS) for lower-risk devices and the Well-Established Technology (WET) concept, have been introduced, **the overall lack of proportionality has significantly increased costs at all steps of the lifecycle,** impacting the availability of devices. This is especially true for the initial certification of a device, where risk classification has actually minimal impact : even low-risk devices must meet stringent requirements, including redundant clinical data validation, even for long-established and demonstrably safe products.

This paper examines the current situation, acknowledging the ambition and strength of the MDR while highlighting its shortcomings, particularly in proportionality, clarity of requirements, harmonization, and excessive administrative burden with limited benefits. EuromContact calls for concrete measures to allow:

- **A truly risk-based approach** that ensures proportionality for devices with long-established safety records. Key requirements, such as clinical evidence, biocompatibility testing and post-market surveillance should be adapted based on a device's safety history.
- A **focus on patient safety and quality rather than excessive bureaucracy**.
- **Clarification of the requirements for better harmonization** in MDR implementation.

EuromContact specifically advocates for the **possibility to demonstrate that legacy contact lenses and lens care products can be considered as WET** under MDCG 2020-6. This would facilitate evidence leveraging, support the use of the "equivalence" concept, and proportionally adjust regulatory requirements.

As the transition period nears its end, some measures are more urgent than others, as they would specifically benefit the remaining devices undergoing certification. This is particularly true for the scope of WET and clinical evidence requirements.

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EuromContact represents the manufacturers of contact lenses and lens care products, which are respectively **class IIa and class IIb devices** under MDR.

Contact lenses are designed to correct refractive vision errors such as myopia, hyperopia, astigmatism, and presbyopia. Soft contact lenses, made of hydrogel or silicone-hydrogel, have a well-documented history dating back to 1961 and 1999, respectively. Their design remains stable, with incremental improvements over decades. Rigid contact lenses provide better visual acuity for people with an abnormal corneal shape. Contemporary rigid contact lenses are manufactured from polymers which are typically composed of around 10 different ingredients selected to impart beneficial properties. The development of this range of oxygen-permeable rigid materials dates back to the late 1970s through the 1990s. Extensive post-market surveillance consistently shows a strong safety record of both soft and rigid contact lenses, with adverse events being rare and typically linked to improper use rather than design flaws.

Lens care products, designed for cleaning, disinfecting, rinsing, and storing contact lenses, have been available for over 25 years. Their formulation consists of well-known, safe compounds, and the field has seen minimal changes in the past two decades. These products have a long-established safety profile.

This paper focuses on the impact of the MDR on such stable medical devices with a long-established safety record.

1. Identification and traceability

State of play

The MDR has significantly increased data requirements for medical devices, **improving transparency but creating disproportionate burdens for low-risk devices with long-standing safety records**. The main challenges in this area are :

- **UDI Implementation :**
  - While lens care products could assign a UDI-DI as any other medical device, **the Master UDI concept was introduced for contact lenses** to reduce the number of entries in EUDAMED, **required industry adjustments but offers no direct patient safety benefits**. For **Made-to-Order** contact lenses, grouping UDI-DIs was necessary to manage the numerous possible combinations of devices, making Master UDI **a welcome solution for these devices**. But for

standard contact lenses, a regular UDI-DI would have provided strict traceability without unnecessary complexity.

- The Master UDI concept was defined long after Basic UDI and UDI-PI, so contact lens manufacturers had already anticipated Basic UDI and UDI-PI assignment based on existing guidance. The same rules should apply to contact lenses as to other medical devices as far as Basic UDI and UDI-PI are concerned.
- Despite requiring extensive data input, there are doubts that Master UDI will provide meaningful benefits to patients, as it is unclear whether they will actively scan and verify this information.

- **Labeling requirements:**
  - The small size of contact lens packaging makes it **difficult to comply with the additional labeling requirements** of MDR, particularly when other EU regulations encourage packaging size reduction.
  - **Frequent changes to labeling requirements** (e.g. sorting information, EC Rep/EU Rep…) create logistical and cost burdens, which can ultimately affect device availability.
  - Excessive information on labels does not necessarily improve patient safety and may contribute to confusion.

- **EUDAMED Registration of devices :**
  - **Frequent updates and changes have kept processes in Eudamed from stabilizing,** making it challenging for manufacturers to establish internal workflows for database population in production. Version updates often impact previous registration efforts, requiring repeated adjustments
  - The **storage and record-keeping requirements for UDI are disproportionate for low-risk devices,** mandating the retention of extensive detailed information for an extended period despite the minimal associated risks.
  - For SMEs without machine-to-machine systems, **the manual registration of each device, often with similar specifications, requires extensive data entry**, frequently duplicating information
  - Delays in EUDAMED availability have **forced manufacturers to maintain national registrations in some Member States while simultaneously inputting data into EUDAMED**, increasing administrative burdens.

Proposals:

- **Provide further clarification and guidance :**
  - Provide a clearer **definition of higher-level packaging and shipping containers**.
  - Offer guidance (e.g., Q&A document) on **proper EMDN code level application** to prevent inconsistent approaches between manufacturers and Notified Bodies. For contact lenses specifically, clarification includes what to do when more than one code may apply, e.g. lenses approved for both daily wear and extended wear, lenses both medical device and annex XVI.
  - Clarify **UDI traceability in mergers and acquisitions** to ensure regulatory continuity.

- **Improve Eudamed implementation :**
  - EUDAMED, once fully operational, is expected to streamline and centralize registration, **replacing national registrations.**

- **Reduce EUDAMED UDI triggers** that go beyond MDR requirements. Certain fields should be editable to prevent unnecessary new UDI assignments. E.g. changes in lens power outside the initially registered range should not trigger a new Master UDI.
- Enable **device registration duplication** (copying data from an existing record to a new (M)UDI-DI) in EUDAMED to improve efficiency. For example, when the only difference is a different base curve there should not be a need to re-input all the same information.

- **Ensure stability:**
  - **Retain current Master UDI system but avoid expanding** it to other jurisdictions or device types.
  - **Prevent additional traceability layers** (e.g., Digital Product Passport), as MDR already ensures sufficient oversight.
  - Maintain **MDCG 2018-1 as the prevailing reference for Basic UDI assignment.**

2. Classification and certification

State of play

The MDR has significantly reinforced the conformity assessment process for medical devices, introducing stricter clinical evaluation requirements and expanding technical documentation obligations. **While these measures aim to enhance patient safety, they can become overly bureaucratic for stable, long-established devices with extensive market surveillance records proving their safety.** Despite the MDR's emphasis on proportionality, the certification process often treats all devices as if they were Class III, imposing excessive documentation requirements on devices that have been safely used for decades. **Class IIa and IIb devices undergo scrutiny comparable to high-risk devices** : the depth of the QMS assessment and the review of technical documentation for these devices is not adjusted according to the risk classification.

As a result, manufacturers, particularly SMEs, face rising compliance costs that can force market withdrawals, not due to safety concerns but because the economic burden becomes unsustainable. Under the MDD, manufacturers could rely more on post-market data, making the clinical evaluation process more balanced. The MDR now requires **extensive formal documentation, often without adding new safety insights** for contact lenses and lens care products because the clinical data remains unchanged year after year, making the repeated documentation process redundant.

Limited issuance of certificates under MDR Article 16 is also to be noted.

The main challenges are :

- **Excessive reliance on formal documentation and continuous testing** for stable devices, instead of leveraging available surveillance data. Unlike in the US, manufacturers cannot leverage anything in the clinical review under MDR.
- **Overly formal administrative requirements** (e.g., rejected electronic signatures) increase costs and delay device availability without improving safety.
- **Every device modification is treated as substantial**, even switching suppliers for identical materials.

- **Inconsistent interpretation of Annex VII requirements** by Notified Bodies, leading to:
  - varying criteria for technical documentation review;
  - inconsistent queries across different documents within the same technical file;
  - shifting requirements between pre-application and technical review phases.
- **Lack of harmonization and clear governance**, making it unclear whether stricter requirements originate from the NB or national competent authority.
- **Excessive approaches on sampling plans**, reducing the intended proportionality.
- **No clear guidance on post-certification modifications**, causing:
  - divergent definitions of significant/substantial change across NBs;
  - mandatory notification of all changes, even minor ones;
  - lack of predictability in modification approvals;
  - delays in implementing updates (e.g., some changes must be reported a year in advance).

As a consequence, the certification process is characterized by :

- **Constantly evolving and inconsistent procedures** across NBs and competent authorities.
- **Unpredictable and extended timeline** for pre-application, conformity assessment and certificate issuance phases, with very significant variations across NBs.
- **Significant cost increases**: according to a 2024 EuromContact survey (24 responses), conformity assessment costs rose by 170% under the MDR compared to the MDD.

Proposals:

- **Implement an effective risk-based approach:**
  - Ensure clear differentiation between high-risk new devices and legacy devices with proven safety. **Assessment depth should be adjusted based on risk class and/or device novelty**.
  - Introduce the **predicate device** concept, similar to the US, to streamline assessment for established products.
  - Allow contact lens and lens care product manufacturers to **use previous documentation** and **leverage existing evidence.**
  - Ensure a **uniform framework for sampling plans** while defining **precise sampling criteria** and **reducing the amount of samplings.**
  - **Allow legacy contact lenses and lens care products to demonstrate that they are WET by fulfilling the 4 criteria of MDCG 2020-6**.

- **Improve predictability of the process :**
  - **Set fixed timelines** for pre-application phase, conformity assessment and certificate issuance, **with some flexibility.** For contact lenses and lens care products, the entire conformity assessment process **should be completed within 3 to 6 months**, from agreement signing to certificate issuance. Introduce **clock-stop mechanisms** to ensure flexibility while preventing application cancellations or excessive fees due to procedural delays.
  - **Establish a structured dialogue framework for early-phase discussions, especially regarding clinical evaluation expectations**.

- **Strengthen governance and harmonization:**
  - Improve **harmonization of procedures and documentation** across competent authorities, notified bodies, internal NB teams (to avoid inconsistencies within the same NB).

- **Maintain Annex II's technical documentation framework**, as it provides clarity and structure.
- **Ensure alignment between NBs and competent authorities to avoid obstacles in leveraging evidence.**
- Clarify that **QMS re-certification should not be a repetition of initial certification**.
- Provide clearer guidance on assessing post-certification modifications and the concept of "substantial change", ensuring that **manufacturers determine if a change is substantial**.
- Establish a **transparent, standardized process for device modifications**:
  - **Faster reviews for substantial changes**.
  - **Non-substantial changes should be reviewed during annual surveillance audits** instead of requiring immediate NB notification.

- **Improve the practicality of MDR Article 16** (Relabeling & Repackaging):
  - Provide **clear procedural guidelines** (e.g., a standardized template).
  - **Remove the last section of Article 16**, which imposes unnecessary restrictions on relabeling and repackaging.

3. General Safety and Performance Requirements

State of play

Manufacturers of all medical devices, regardless of classification, must ensure compliance with the General Safety and Performance Requirements (GSPRs). But medical devices encompass a **broad range of products with varying risk profiles, complexity, and stability**.

Key challenges include :

- **Application of some specific GSPRs** :
  - "substances" (Chapter II) **Current biocompatibility testing requirements are disproportionate for stable, long-established materials**. Rigid contact lenses, for example, are produced using the same monomer mixtures across manufacturers, yet each manufacturer must repeatedly conduct identical tests, despite consistent results. These tests require significant time, resources, and investment, which is particularly burdensome for SMEs, while post-market surveillance data already provides sufficient safety insights, making repetitive testing redundant. Most manufacturers, especially SMEs, do not have access to toxicologists. In the US, the FDA allows shared use of biocompatibility studies.
  - "Requirements regarding the information supplied with the device" (Chapter III) The MDR has **significantly increased labeling requirements**, leading to information overload that does not improve patient understanding. Small device packaging, such as contact lens packaging, is particularly affected. E-labeling solutions remain stalled, leaving manufacturers with limited options to address space constraints. Beyond MDR, manufacturers must comply with **continuous labeling updates** due to regulatory changes (e.g., recycling logos…). Each **label modification requires review**, adding significant costs and creating a risk of product withdrawals, depriving patients of medical solutions.

- **The lack of clarity and harmonization of the process to comply with GSPRs :**
  - GPSR checklists are overly complex.
  - There is no clear and harmonized process for demonstrating compliance across NBs.
  - The **publication of harmonized standards** based on ISO standards is currently on hold, preventing manufacturers from relying on product-specific standards to benefit from the presumption of conformity.

Proposals:

- **Proportionality in biocompatibility testing:**
  - Accept justifications to **waive annual testing when the same material is used, and devices have a long, proven safety record.**
  - Allow **one material extraction study** to cover all manufacturers using the same material.
  - Adopt a **substantial equivalence approach** for long-standing devices.

- **Strengthen harmonization and consistency:**
  - Provide **clear guidance on GSPR checklists** to simplify compliance.
  - Ensure **consistent interpretations** from notified bodies.

- **Promote the regulatory acceptance of digital labeling** (e-IFU and digital label).

- **Ensure regulatory stability:**
  - **Reduce the burden of frequent labeling changes** and **streamline their review process**
  - Avoid **referencing specific standard versions** in GSPR checklists, as frequent updates create unnecessary compliance burdens.

4. Clinical Investigation and Evaluation

State of play

The **MDR has significantly strengthened clinical evidence requirements** to enhance patient safety. **While this objective is important, the requirements are disproportionately burdensome for stable devices with a long history of safe use**.
With the **ongoing transition to MDR**, manufacturers **urgently need clarity** on clinical evaluation expectations.

Key challenges include:

- **Lack of clarity, predictability, and harmonization:**
  - The **MDCG guidance on clinical evaluation is still not available**, whereas clinical evaluation is a central element of conformity assessment. Manufacturers **need clear criteria** to specify and justify the **level of clinical evidence** required.
  - **Inconsistent definitions of "sufficient clinical evidence"** across NBs.
  - Inconsistent approach across NBs regarding the concept of “equivalence”. Many NBs insist that equivalence requires an identical device, making it **nearly impossible to claim equivalence**

because a manufacturer cannot demonstrate that the device of a competitor is identical. In contrast, FDA criteria are more flexible in defining equivalence.
    - **Classification as WET varies**: some NBs only accept WET devices listed in the MDR, while others accept devices that meet the 4 criteria outlined in MDCG 2020-6. Lens care products and contact lenses can be considered as WET according to the criteria in MDCG 2020-6.

- **Excessive documentation burden**:
    - Manufacturers must **demonstrate identical technical, biological, and clinical characteristics**, requiring extensive studies to document the technical file.

Proposals:

- **Further clarify to foster harmonization**
    - Provide **urgent guidance on what constitutes "sufficient clinical evidence"**
    - Clarify **equivalence criteria to be based on similarity** rather than identical design.
    - Define **clear expectations for Article 61(10)** regarding clinical evaluation requirements.

- **Proportionality: allow legacy contact lenses and lens care products to demonstrate that they are WET by fulfilling the 4 criteria of MDCG 2020-6**. This would allow for more proportionate requirements (possibility to leverage evidence, adapted PMCF requirements, no need to demonstrate equivalence with other products for clinical evidence…).

- **Improve predictability :** allow manufacturers to **discuss clinical strategy with NBs before submission** as requirements should be consistent across NBs. Early discussions would enable manufacturers to plan clinical investigations efficiently while it takes time to do investigations. The FDA allows pre-submission meetings where they share feedback on clinical strategy before formal submission.

5. Post-Market Surveillance and Vigilance

State of play

Post-market surveillance (PMS) is a **well-structured and valuable tool** under the MDR, addressing gaps in the MDD and enabling a **more effective lifecycle management system**. PMS provides crucial real-world data and clinical feedback, allowing manufacturers to improve product quality and technical documentation. However, for contact lenses and lens care products, the current PMSV requirements are disproportionate despite the fact that Article 83.1 emphasizes the principle of proportionality : they are treated as if they were Class III devices, leading to e**xcessive documentation, redundant reporting and overlapping PMSV processes.** A **more flexible, risk-based approach** is necessary, focusing on **data quality rather than quantity**.

Key challenges include :

- **Over-reporting for low-risk devices**
    - **Duplication across PMS documents** (PMCF Plan, PMCF Report, PSUR, PMS Plan).

- **Frequent and inconsistently defined PMS document updates.** MDR only defines annual PMCF updates for Class III and implantable devices. Some NBs require PMCF updates at the same frequency as PSUR, adding unnecessary burden.
- **Short reporting timelines** (2/10/15 days) versus 30 days in other jurisdictions. This forces manufacturers to submit **3 separate reports** (initial, interim, and final), increasing administrative burden without adding safety value.

- **Redundant vigilance report reviews**
  - Manufacturers must **submit all vigilance reports to NBs**, even though market surveillance is the responsibility of national competent authorities.
  - NBs charge **fees for each vigilance report review**, adding significant costs.
  - Some NBs request modifications to reports already reviewed by competent authorities, further increasing **administrative complexity**.

- **Difficult and delayed transition to EUDAMED**
  - The new **MIR form (7.3.1) is not compatible with EUDAMED**, creating additional administrative challenges.
  - Manufacturers **do not always receive complete information** required for EUDAMED submissions (e.g., exact device identification).
  - A **fully functional EUDAMED system is necessary** to streamline PMSV processes.

- **Limited feedback quality**
  - The quality of feedback from PMSV reports is **not yet optimal**. Reporting often fails to provide actionable insights.
  - It remains **challenging to distinguish between user-related and manufacturing-related issues**.

Proposals:

- **A more flexible, risk-based approach**
  - **Reduce the number of required reports for lower risk devices**, prioritizing the quality of information over quantity :
    - by merging PMS plan and PMCF Plan
    - by requiring only a single report (PSUR, eliminating the need for a separate PMCF report)
  - **Review report update frequency** : Annual PMCF report updates (as expected by NBs) should not be required for Class IIa and IIb devices if no new clinical data affecting the benefit-risk profile is available.
  - **Extend reporting deadlines** for low-risk devices.
  - **Eliminate redundant vigilance report reviews** without compromising patient safety, NBs already receive continuous information via PSUR.

- **Improve EUDAMED implementation**
  - **Ensure full compatibility of MIR form (7.3.1) with EUDAMED**.
  - Deliver as soon as possible **full EUDAMED deployment** to improve reporting efficiency

- **Provide clearer guidance**

- Develop **more specific guidance on trend reporting**, ensuring manufacturers understand how to conduct trend analysis effectively.

6. Annex XVI devices

State of play

Non-corrective colored contact lenses are now listed in Annex XVI and therefore in scope of MDR.

With the publication of MDCG 2023-5 guidance, which introduced the **concept of "dual-purpose device" for corrective colored contact lenses** (which have a medical purpose), the situation has become more complex : these medical devices are supposed to comply with Annex XVI common specifications too. While the MDR was designed to enhance user safety by broadening its scope to include cosmetic and beauty products, this **duplication of requirements for contact lenses whose principal intended purpose is medical is unnecessary**, and these products have been on the EU market as medical devices under MDD for years.

Key challenges :

- This **classification as "dual-purpose device" has created significant regulatory burdens for manufacturers.**
  - Corrective colored contact lenses, which were already medical devices under MDD, now must comply with Annex XVI common specifications **on top of MDR requirements**
  - Almost all manufacturers of colored contact lenses **decided not to transition their products to MDR** due to the excessive burden (as shown in the Goeg survey, slide 54).
  - **Higher regulatory costs** make the business model financially unsustainable, effectively pushing these products, despite their long, safe history under the MDD, out of the EU market.

- **For non-corrective colored contact lenses** (without any medical purpose), **meeting common specifications is also problematic:**
  - **Inconsistent interpretations of requirements** across NBs.
  - **NBs lack expertise in Annex XVI common specifications**, leading to uncertainty in the assessment process (e.g., QMS review…)

Proposals:

- **Remove the dual compliance burden** : corrective colored contact lenses should be subject only to MDR requirements, removing the need to comply with Annex XVI common specifications. **MDR alone should be sufficient for these products to be marketed in the EU.**

- **Establish a clear, standardized and predictable certification process for Annex XVI products.**

7. Miscellaneous

- **Economic operators verification**
  - Currently, if a manufacturer, importer, and distributor belong to the same organization, they must undergo separate verification checks for each role. This results in **duplicated work** and unnecessary administrative burden.
  - ↳ **Proposal: avoid redundant checks within the same organization** when it acts as both importer and distributor (revision of MDCG 2021-27 Rev.1).

- **Governance & harmonization**
  - **Divergent interpretations** between manufacturers, notified bodies and competent authorities create regulatory uncertainty. There is **no clear decision-making body to resolve disputes,** leading to delays and inefficiencies.
  - ↳ **Proposal: Make a single entity with the authority to resolve disagreements and ensure consistent interpretations.**

- **Digitalization**
  - ↳ Allow **electronic Instructions for Use (eIFU)** for **contact lenses**
  - ↳ Accelerate adoption of **e-Labeling** for information on the label that in not needed for the safe use of the device., CE certificates
  - ↳ Enable **digitalization of documents and signatures** (e.g. Digital Free Sale Certificates, CE certificates…)