COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR High Level Contribution
on the Proposal for Medical Devices Regulation
Revision of Directive 2007/47/EC

NEW 7 Sept

Introduction

COCIR, the voice of the European manufacturers of medical imaging, radiotherapy, health ICT and electromedical industries, welcomes the revision of the current Medical Devices Directive (MDD) and its replacement with the proposed Medical Devices Regulation (MDR). The proposed MDR should build on the many merits of the existing regulatory approach while remaining robust, transparent and adaptable to scientific as well as technological progress. The primary objective of the revision process must be to achieve an efficient regulation delivering patient safety, high quality and rapid access to innovative medical technology and last but not least build public trust in the proposed Regulation.

The document is a High Level Contribution addressed to all parties involved in the revision process and is based on the latest developments of the proposed MDR [1]. It outlines COCIR's recommendations articulated through 13 strategic points considered of key importance by COCIR. More detailed documents have as well been developed, such as on software and on vigilance.

COCIR recommendations

1. **Vigilance:** keep the scope limited to '*serious*' incidents; ensure clarity and consistency of reporting time frame (e.g. 15 days after becoming aware of the incident is too short); introduce a tailored post-market surveillance system taking into account the medical device's life cycle; clear obligations must be defined for economic operators (various Articles)
2. **Software (as a Medical Device):** ensure software can be classified commensurate with the risk it possesses by ensuring clarity and international convergence (Article 2, Annex VII)
3. **Harmonised standards and common specifications:** maintain the central role of harmonised standards as per current New Approach (Article 6) and use common specifications only in exceptional cases, ensuring input by all stakeholders (Article 7)
4. **Chemicals:** maintain the European Commission's proposal on the management of hazardous substances (Annex I, Point 7.4)
5. **Transparency:** support the European Parliament's proposal to establish a Medical Device Advisory Committee (MDAC) with all stakeholders as contributors (Article 78a)
6. **Scope and definitions:** delete the term '*indirect*' or define its scope; clarify the definition of term '*clinical benefit'*; define the term '*patient management*' (Article 2)
7. **Delegated acts:** maintain legal certainty by limiting the use of delegated acts to cases where they are genuinely needed (various Articles)
8. **Transition period:** manufacturers require a reasonable preparation period; 3 years can only suffice if they can make meaningful preparations throughout this period, starting from the availability of the implementing legislation (Article 97)
9. **Scrutiny procedure:** strengthen the performance of Notified Bodies; minimise and advance any special review of high risk medical devices, where truly needed for patient safety (various Articles)
10. **Unique Device Identification:** support a single European system and database that is aligned with the United States' FDA Final Rule (Chapter 3)
11. **Economic operators:** clarify the various roles and responsibilities and avoid overlaps (e.g. importer versus Authorised Representative) (various Articles)
12. **Clinical data and investigations:** tailor the system to the unique characteristics of medical devices and avoid borrowing from the pharmaceutical model (various Articles)
13. **Reprocessing:** ensure a high level of patient safety by extending all manufacturer obligations and liabilities to reprocessors (Article 15)

[1] European Commission proposal, European Parliament amendments and Council of the European Union General Approach

DETAILED BRIEFING

1. Vigilance

COCIR considers a robust post-market phase a key element in a balanced regulatory framework. Part of such post-market phase is a vigilance system that has unambiguous and fair obligations for all parties involved in the placing on the market and use of medical devices.

In the context of reporting of incidents (Article 61), the European Commission's proposed MDR includes different notions of '*incident*[2]' and '*serious incident*[3]' to what exists under the current MDD, while not impacting the events to be reported. Limiting the reporting by manufacturers to serious incidents (as newly defined) for vigilance purposes is acceptable and proportionate.

However, the European Parliament has proposed that all events meeting the proposed MDR definition of 'incident' will need to be reported in the future.

COCIR considers that this is an extreme and disproportionate expansion of the scope and estimates that it would only result in a huge increase in the number of manufacturer reports.

The vast majority of these new reports would be routine corrective maintenance calls that are not relevant for patient safety or user safety and COCIR shares the European Commission's concern that it would only render the rapid identification of serious incidents and their proper follow-up more difficult. In addition to the significant administrative burden on manufacturers, it would also overload both Competent Authorities (CAs), who must conduct a risk assessment on reported events, and Notified Bodies (NBs), who must evaluate the impact on the medical device's certificate. Moreover, for higher class medical devices, there are additional requirements on trend reporting for the incidents that are non-serious incidents, which would anyhow allow CAs to react on an increase of frequency or severity of such incidents.

COCIR strongly believes that by keeping such reports limited to serious incidents – as is the case in the current MDD – the information uploaded to the electronic system will remain focused on patient safety and Member States' post-market surveillance activities, ensuring that only relevant incidents are provided to the CAs.

COCIR appreciates the European Commission proposal whereby reporting by the manufacturer of the medical device is needed only when a causal relation between the serious incident and the medical device is probable. Otherwise, serious over-reporting is likely to occur. Reducing the reporting time frame from 30 days to 15 days can be supported by COCIR only if this time frame starts at the moment when the manufacturer becomes aware of the serious incident. In this context, COCIR would like to shed some light on the findings of the Global Harmonization Task Force (GHTF) study conducted by the Study Group 2 entitled '*Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*' (30 November 2006)[4]. According to the study, more than 50% of the events need more than 15 days to be investigated. COCIR believes that these findings are still valid and in order to challenge them, a new study needs to be conducted.

While stated in the economic operators obligations related articles, the role of distributors and importers in notifying serious incidents to manufacturers is not sufficiently addressed (in Chapter VII). Their cooperation is of utmost importance in order to ensure a robust post-market vigilance system. It is important to fully secure cooperation and support from them for incident evaluation and specific obligations should be added, highlighting the necessity of their contribution (e.g. criteria and timeframe to report to manufacturers).

---

[2] *Article 2(1)(43): '**incident**' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, **any** inadequacy in the information supplied by the manufacturer and any unexpected undesirable side-effect*

[3] *Article 2(1)(44): '**serious incident**' means any **incident** that directly or indirectly led, might have led or might lead to any of the following:*
*– **Death** of a patient, user or other person*
*– Temporary or permanent **serious deterioration** of the patient's, user's or other person's state of health*
*– Serious public **health threat***

[4] GHTF/SG2/N54R8:2006

COCIR supports maintaining a post-market surveillance system during the lifetime of the medical device as both patients' and users' safety needs to be guaranteed (Article 60a 3). However, the requested information needs to be tailored, taking into account the medical device's life cycle status (e.g. for equipment: being placed on the market, not placed on the market anymore but under manufacturer's support and out of manufacturer's support).

Finally, in the context field safety corrective actions (Article 63), COCIR supports the need to inform users in a timely manner and insists on the fact that all the economic operators and not only the manufacturer need play their part in ensuring traceability and corrective actions deployment.

COCIR recommendation(s): keep the scope limited to '*serious*' incidents; ensure clarity and consistency of reporting time frame (e.g. 15 days after becoming aware of the incident is too short); introduce a tailored post-market surveillance system taking into account the medical device's life cycle; clear obligations must be defined for economic operators.

2. Software (as a Medical Device)

COCIR would welcome the integration of the IMDRF definition for Software as a Medical Device and the establishment of a dedicated classification rule for software-only products (not embedded in medical devices) based on the IMDRF risk categorisation in the proposed MDR.

Due to the Council of the European Union's General Approach, now only one classification rule applies to software (Rule 1). This implies that all software that is a medical device in its own right is class I. This makes that e.g. high risk software for computer aided diagnosis, detection or screening does not have to pass via Notified Bodies (NBs) in order to be placed on the market. This is not in the interest of public health and deviates from the position of the rest of the world, where such software is typically considered as belonging to a higher risk class.

Using the rules for active devices as defined by the current MDD (Rules 9-12) by stating software is considered an 'active' device does not provide a solution. These rules are based on a degree of invasiveness and area/time of contact with the body, something that does not apply to software-only products.

Instead, COCIR suggests a new classification rule to be added to Annex VII specific for '*Software as a Medical Device (SaMD)*' as defined by the IMDRF. This rule should not apply to '*Software for a Medical Device (SfMD)*', for which the existing rules are applicable.

COCIR recommends basing this new classification rule on the *'IMDRF risk categorisation for Software as a Medical Device*'. The IMDRF risk categorisation has been developed to provide regulators with a framework to allocate a regulatory class to a risk type, which is commensurate with the risk of the software. The IMDRF risk category framework considers the medical purpose of the product and the context of use for the product – as stated by the manufacturer.

COCIR recommendation(s): ensure software can be classified commensurate with the risk it possesses by ensuring clarity and international convergence.

3. Harmonised standards and common specifications

A reliable and simple regulation is essential to ensure a safe and equitable access to healthcare across the European Union. Such a regulation is best supported by '*state of the art*' standards - developed by all concerned stakeholders in agreement - that cover the relevant essential requirements. Such standards are – and must remain – the preferred tool to support compliance with European legislation.

COCIR is, since 2010, concerned with the very slow and burdensome harmonisation of standards process. Considering that the proposed MDR will require '*re-harmonisation*' of all standards, a practical process needs urgently to be defined.

COCIR is not in favour of a '*common specifications (CS) for all*' approach: content, required expertise and drafting mechanisms are very different (e.g. technical, clinical and reprocessing of single-use medical devices). For these reasons, COCIR proposes not to mix them up.

COCIR also recommends that drafting processes are specified for each category of CS, ensuring ample input by all concerned stakeholders.

Furthermore, COCIR considers that the proposed concept of CS should only be used when no relevant harmonised standards exist. Therefore, COCIR supports the European Parliament's proposed amendment of Article 7(1). This amendment limits the range of scenarios in which CS are acceptable.

COCIR recommendation(s): maintain the central role of harmonised standards as per current New Approach and use common specifications only in exceptional cases, ensuring input by all stakeholders.

4. Chemicals

The current MDD ensures that the use of hazardous substances in medical devices is subject to a risk-benefit analysis, performed by the manufacturer.

The proposed MDR seeks to strengthen this system, by addressing additional substances such as endocrine disruptors and improving the functioning of NBs.

The European Commission's proposal is effective for ensuring that medical devices are safe and that hazardous substances are only used in cases where feasible alternatives, providing equal benefits for patient safety, are unavailable. Moreover the European Commission's proposal allows for a proper enforcement and verification without overburdening manufacturers, NBs and the CAs' inspection staff.

We deem it extremely important that Members States, the European Commission and the European Parliament be aware and in full agreement that there is no need for additional provisions on chemicals to ensure the safety of medical devices.

COCIR recommendation(s): maintain the European Commission's proposal on the management of hazardous substances.

5. Transparency

COCIR values the establishment of the Medical Device Coordination Group (MDCG) as a group of representatives of Member States, supported by the European Commission, tasked to coordinate and to harmonise activities amongst Member States and to contribute to the elaboration of European guidance.

We believe that the currently established Medical Device Expert Group (MDEG), including all stakeholders as contributors, has proven its value over the years. We consider that stakeholders, including industry, should not be relegated to an observer role but should remain as active contributors.

For this reason, COCIR greatly welcomes the European Parliament's proposal to complement the MDCG with a multidisciplinary Medical Device Advisory Committee (MDAC) (Article 78a) that includes stakeholders' experts and representatives in order to provide support, advice and expertise to the MDCG on different aspects of the proposed MDR.

COCIR supports an efficient communication process, which would concur to improve patients' and users' safety. Nevertheless, access to vigilance and other relevant information should be organised in order to protect privacy, confidentiality and intellectual property. COCIR is also concerned by making such information accessible either too early or to a too large public, could lead to disclosure of incorrect information and/or unnecessary concerns.

COCIR would welcome a definition of appropriate access levels for public but also of appropriate access levels for healthcare professionals as well as making the information accessible only after being reviewed and approved by CAs.

COCIR recommendation(s): support the European Parliament's proposal to establish a Medical Device Advisory Committee (MDAC) with all stakeholders as contributors.

6. Scope and definitions

COCIR is concerned by the European Parliament's proposed amendment to the definition of 'medical device' (Article 2.1(1)) to include devices with 'indirect' medical purposes and welcomes the Council of the European Union's General Approach of keeping the European Commission text in this respect.

In combination with the definition of '*accessory to a medical device*' (Article. 2.1(2)), this could unintentionally include too many devices, such as:

- general purpose, non-medical software, and
- consumer electronics like smartphones and tablets

into the scope of the proposed MDR.

More generally, the imprecise nature of the term '*indirect*' represents a risk of provoking many new disputes about how to regulate borderline devices. Many such disputes have taken place in the context of the current MDD, and the proposed MDR should aim to correct, rather than exacerbate, this situation.

To avoid this situation the term 'indirect' should be deleted, or at least the legislator should provide an exact and precise definition on its scope.

The European Parliament's proposal includes several new definitions in respect to the European Commission's proposed MDR. COCIR supports any clarification that can potentially lead to a better understanding of the proposed MDR and suggests aligning such definitions as much as possible to the ones already used in the international landscape.

COCIR has some strong concerns regarding the inclusion of the term '*clinical benefit*' in the definition of clinical performance (Article 2, 37d) as proposed by the Council of the European Union's General Approach. It remains rather unclear how the '*clinical benefit*' could be justified for so called '*low-end/low price*' medical devices in comparison with '*high-end/highly sophisticated*' medical devices with similar or the same intended use(s). Would it mean that '*low-end/low price*' medical devices will disappear from the market since their '*clinical benefit*' to the individual patient and to the patient management of a healthcare facility would be lower than compared with '*high-*'*end/highly sophisticated*' medical devices?

In addition, the term '*patient management*' is not defined and could be interpreted differently, for e.g. workflow in a healthcare facility or treatment planning of an individual patient.

COCIR recommendation(s): delete the term '*indirect*' or define its scope; clarify the definition of term '*clinical benefit*'; define the term '*patient management*'.

7. Delegated Acts

The proposed MDR frequently refers to Delegated Acts and this creates substantial regulatory uncertainty. COCIR suggests limiting their use to only non-essential elements of the proposed MDR, in accordance with Article 290 of the Treaty of Lisbon[5].

Therefore, COCIR strongly supports the European Parliament's proposals to avoid modification of the General Safety and Performance Requirements (Article 4.5), the technical documentation rules (Article 8.2) and the conformity assessment procedures (Article 42.11) via Delegated Acts.

Nonetheless, COCIR remains concerned over the fact that the European Commission retains the power to amend or supplement the Annex VII classification criteria (Article 41.4) and the lack of consultation of stakeholders in this process.

It may be justified in special cases to use delegated acts to decide that a medical device (or category/group thereof) should be classified in another class, by way of derogation from the classification criteria. However, amending or supplementing the classification criteria should only happen through the full EU legislative procedure involving all institutions and stakeholders.

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E290:EN:HTML

In general, COCIR supports the significant efforts made, for more than twenty years, in order to harmonise requirements at international level. Definitions of core terms, and classification of medical devices into risk classes, should therefore match as much as possible the European commitments at international level, particularly within the International Medical Device Regulators Forum (IMDRF). These efforts have included a definition of Software as a Medical Device (SaMD) and a related risk categorisation. Additionally, the Delegated Acts should properly define the processes and be easily understandable.

COCIR recommendation(s): maintain legal certainty by limiting the use of delegated acts to cases where they are genuinely needed.

8. Transition period

A 3 year transition period is only sufficient for industry if economic operators are able to make full use of this time and if it is starting to run as from the availability of the implementing legislation. For many obligations, it is only possible to start making meaningful preparations after other parts of the proposed MDR have been implemented, e.g. once a NB has been re-notified, or once a delegated act or implementing act has been published (for an example, please see below).

The proposed MDR should recognise this reality and specify that the 3 year period starts to run only once preparations within companies can meaningfully begin. If this does not happen, economic operators risk falling out of compliance, or even to be punished, for factors outside their control. Moreover, in many third countries, medical device registration is based on CE marking. In these markets, it will be necessary to re-register medical devices due to updated labels, technical files, and declarations of conformity and EC certificates.

To correct this issue, COCIR recommends the modification of the derogations in Article 97(3). The modified Article should list all provisions for which an implementing legislation will be published, and specify that the transition period for those is 3 years after the implementing legislation's date of application.

COCIR recommendation(s): manufacturers require a reasonable preparation period; 3 years can only suffice if they can make meaningful preparations throughout this period, starting from the availability of the implementing legislation.

9. Scrutiny procedure

In COCIR's view, the best way to strengthen the existing CE marking process is to increase the overall level of performance of NBs. This can be achieved by raising the standards by which NBs are designated and reviewed.

The European Commission's Implementation Recommendation of September 2013[6], which brings forward the 2012 joint plan for immediate action[7] following the PIP scandal, is going into this direction, as are certain elements of the Council of the European Union's General Approach.

The creation of a new category of NBs, with separate designation and review procedures, must be avoided. This would create an artificial dichotomy in the system, with manufacturers possibly having to refer to different NBs for medical devices in the same therapeutic categories. It could also give the false impression that medical devices evaluated by '*conventional*' NBs are less safe than medical devices evaluated by 'new' categories of NBs. This would undermine the trust in the entire regulatory system.

COCIR remains concerned about both the European Commission's and the European Parliament's proposals for additional pre-market scrutiny. Both proposals add unnecessary and unpredictable delays for life-saving medical devices, and thereby risk seriously undermining patient safety, innovation and competitiveness.

[6] *http://europa.eu/rapid/press-release_IP-13-854_en.htm*
[7] *http://europa.eu/rapid/press-release_IP-12-119_en.htm*

The process for clinical evaluation consultation, as specified in section 6.0 of Chapter II of Annex VIII or Section 6 of Annex IX of the Council of the European Union's General Approach addresses COCIR's objection regarding unpredictability, but still could cause unnecessary market access delays. This objection could be resolved by replacing the process for clinical evaluation consultation by analogous provisions as proposed for in vitro diagnostics (IVDs) in Article 42 of the Council of the European Union's General Approach on proposal for a Regulation on in vitro diagnostic medical devices[8].

COCIR recommendation(s): strengthen the performance of Notified Bodies; minimise and advance any special review of high risk medical devices, where truly needed for patient safety.

10. Unique Device Identification

COCIR welcomes the European Parliament's call for a single European Unique Device Identification (UDI) system and database (Article 24.1) and not multiple systems across the European Union.

COCIR also welcomes the European Commission's April 2013 Recommendation[9], which called for a common European UDI framework and warned Member States against launching national UDI initiatives in isolation of each other.

To enable true worldwide traceability, the single European system should be aligned as much as possible with the UDI system recently put in place via the United States FDA's Final Rule.

The core UDI features, including the label and the data elements for the European database, should be as interoperable as possible with what exists in the United States.

Despite the European Parliament's welcomed amendment on coherence with global UDI and the Council of the European Union's General Approach specifying the transition times for the different risk classes, important details are still missing from the proposed MDR regarding who will administer the single European system and how many entities the European Commission will designate to assign UDIs.

If these details cannot be specified in the proposed MDR, they should be clearly laid out in the forthcoming delegated act.

To give but one example, provisions on UDI are only given in general detail in Chapter III. Much of the detail regarding UDI will only be given at a later date, in the form of a delegated act. Either this delegated act, or the proposed MDR itself, will need to specify that the corresponding obligations only apply 3 years after the delegated act enters into force.

COCIR recommendation(s): support a single European system and database that is aligned with the United States' FDA Final Rule.

11. Economic operators

The roles and responsibilities of all economic operators need to be as clear and distinct as possible.

In COCIR's view, certain of the described tasks overlap each other and thus add unnecessary administrative burden, with no obvious benefit for the patient safety. In particular, the obligations of importer versus Authorised Representative (AR) need further clarification (Article 9 and Article 11).

For imported medical devices, COCIR considers that since ARs have to be assigned for medical devices, it is duplication to ask importers to identify themselves, unless importers do not have any contracts with ARs and/or manufacturers. In order to ensure a smooth operation of the post-market vigilance system, only the details of the manufacturers AR in the European Union should be featured on the medical device label (Article 11.3).

[8] http://data.consilium.europa.eu/doc/document/ST-9770-2015-INIT/en/pdf
[9] *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF*

In addition, European Parliament's proposal and Council of the European Union's General Approach for the words 'medical device' to accompany the CE marking is unnecessary and overly burdensome, as economic operators would need to translate these two words into the 24 official languages of the European Union when labelling their medical devices (Article 18). On the contrary, COCIR considers that the role of economic operators related to post-market surveillance is not consistently and sufficiently described. Clear obligations to notify potential serious incidents to manufacturer and to facilitate, cooperate and support Field Safety Corrective Action deployment should be included.

COCIR recommendation(s): clarify the various roles and responsibilities and avoid overlaps (e.g. importer versus Authorised Representative).

12. Clinical data and investigations

COCIR firmly believes that clinical investigations for medical devices are fundamentally different from clinical trials conducted in the pharmaceutical world. As such, we are concerned about the various proposals, from all the three European Institutions, that seem to incoherently borrow ideas from the recent review of the Clinical Trials Directive for medicinal products (Directive 2001/20/EC).

Additionally, they do not readily fit with the globally accepted concepts set out in EN ISO 14155 'Clinical investigation of medical devices for human subjects -- Good clinical practice'. Furthermore, we strongly recommend adhering to the New Approach concept. Mirroring an internationally recognised standard into the proposed MDR, as done in the Council of the European Union's General Approach, does not allow timely alignment with necessary changes in the applicable good clinical practice. This can be only assured using international standards which are reviewed by international key expert committees, as required, and thus represents the internationally agreed state of the art.

Moreover, COCIR has major concerns about the ethical aspect of clinical investigations conducted on humans, since the reference to the Declaration of Helsinki has been removed from the Council of the European Union's General Approach (Annex XIV, Article 1).

We are particularly concerned about the European Parliament's proposal for mandatory submission of clinical investigation results to an electronic system that will be made partially available to the public (Article 57.3). Full clinical investigation reports should only be accessible to professionals who are able to understand them, and commercially sensitive information potentially present in these reports must be protected whenever access is granted to the electronic system.

COCIR is also concerned by the following issues raised by the Council of the European Union's General Approach:

- **Obligatory clinical investigations for all implantable and class III devices**
  Clinical investigations are mandatory for all implantable medical devices and medical devices falling within class III. Several well-known medical devices, such as radioactive seeds (previously AIMDD) would now require a clinical investigation, although its conformity to safety and performance requirements could very well be demonstrated by a clinical evaluation. In this case, NBs shall check if the Post-Market Clinical Follow-up plan is appropriate in order to confirm that the benefit/risk ratio is not affected and includes post market studies to demonstrate the safety and performance of the medical device.

- **Limitation of equivalence claim on a medical device from another manufacturer**
  It is only allowed to claim equivalence to a medical device of another manufacturer, if both manufacturers have a contract in place allowing full access to Technical Documentation of the another manufacturer (Article 49, 2a). This requirement would practically limit the available clinical data to manufacturer's own medical devices, as the Technical Documentation contains commercially highly sensitive information. COCIR is very concerned because of potential competitive advantages of large manufacturers, which have large product portfolio compared to companies with small product portfolio, such as Small and Medium Enterprises (SMEs). This limitation of equivalence is not needed, as the manufacturer is able to assess the equivalence with regards to clinical use and technology without having full access to Technical Documentation. Furthermore, exposing human subject to unnecessarily to clinical investigations raises ethical objections.

COCIR recommendation(s): tailor the system to the unique characteristics of medical devices and avoid borrowing from the pharmaceutical model.

13. Reprocessing

To ensure a consistently high level of patient safety, it is appropriate that reprocessors of single-use medical devices are subject to the same liabilities and obligations incumbent upon manufacturers of medical devices. Considering single-use medical devices as reusable medical devices by default will endanger public health and is against the proposed MDR's goal of reducing risk as far as possible. Therefore, reprocessors of single-use medical devices must be obliged to adhere to the applicable conformity assessment procedure for the type of device.

COCIR, while understanding the potential economic interest, regrets the proposals by the European Commission as well as by the Council of the European Union to allow for potential measures that are contradictory with the requirements for risk reduction as per Annex I, that are not in line with the principles of the Single Market and that appear to legalise off-label use. A solution may be found by imposing full manufacturer's obligations on reprocessors of single-use medical devices.

Unfortunately, the Council of the European Union's General Approach jeopardises such an approach by allowing reprocessing where permitted by national law. Additionally, the chosen approach is according to COCIR not in line with the principles of the Single Market.

COCIR recommendation(s): ensure a high level of patient safety by extending all manufacturer obligations and liabilities to reprocessors of single-use medical devices.