Recommendations on the use of Guidance Documents Related to the Medical Device Regulation (MDR) and *In vitro* Diagnostics Regulation (IVDR)

POSITION PAPER

MedTech Europe
from diagnosis to cure

Recommendations on the use of Guidance Documents Related to the Medical Device Regulation (MDR) and *In vitro* Diagnostics Regulation (IVDR)

28 June 2022

The MDR and the IVDR provide for multiple instruments and those responsible for implementing these Regulations are increasingly using additional informal publications to inform, enhance, elaborate, or interpret the content of the legal texts. These additional informal publications are referred to in this paper as "guidance documents".

Regulators have claimed to MedTech Europe that these guidance documents cannot come with a "transition period" or "application date" after which compliance with the contained interpretation is expected. Therefore, guidance documents do not have a date or a period from when industry and Notified Bodies are expected to consider the content.

However, it is in many cases unrealistic to transfer newly established expectations from regulators into practice without a minimum period of time that is proportionate to the significance and impact of the change. This includes Notified Bodies who need to introduce the new guidance documents into their quality management systems, which may change their established processes and trigger training of personnel.

While industry is committed to deliver safe and performing devices and complying with applicable laws and Regulations, newly arising interpretations of legal requirements should not put the placing of CE-marked medical devices on the market and the support of patients and healthcare systems at risk, as long as safety and performance of the devices are not compromised.

MedTech Europe therefore calls on the European Commission, Competent Authorities and Notified Bodies to:

1. Recognise that a guidance document is not legally binding and therefore does not need to be applied as if it were mandatory, but instead allows to adopt for use of duly justified solutions which ensure that the overall goal of the guidance document is respected.
2. Minimise the impact of any newly issued guidance document *during* conformity assessment by allowing it to be considered over time in a way that safeguards certification.
3. Avoid that any newly issued guidance document has a negative impact on devices *already* certified by only expecting its content to be first taken into account at the time of re-certification of such devices.

Application of these above recommendations would, we firmly believe, help safeguard against risks of avoidable shortages of devices needed by patients and healthcare systems.

Detailed justification for these recommendations is annexed to this paper.

Detailed Justification

This Position Paper concerns documents that assist stakeholders to implement the Medical Devices Regulation, 2017/745 ("MDR") and the *In Vitro* Medical Devices Regulation, 2017/746 ("IVDR"), jointly referred to as the "Regulations" or individually a "Regulation", as published by the European Commission or its departments and agencies, the MDCG or EU member states, including Notified Bodies. In order to assure market availability of safe and performing medical devices, this Position Paper lays out an industry view on expectations for the use and pragmatic timing of application of such documents.

The Regulations provide for multiple legal instruments and the legislators use additional informal publications to inform, enhance, further detail, implement or interpret the legal content of the Regulations. Examples are:

- European Commission Implementing Decision or Regulation (e.g. Common Specifications),
- MDCG Documents (including documents of its sub-groups),
    - Guidance Documents (incl. Best Practice Documents),
    - Notices,
    - Position Papers,
    - FAQs / Questions & Answers, Help Desks responses and publications,
    - Forms and Templates of required reports, records or registrations,
- Other documents in context of the Regulations, e.g. authored by the European Commission, its agencies or departments, or Member States or its agencies, e.g. SCHEER, CAMD, JRC, etc.
- European Commission Fact Sheets and Infographics,
- Documents issued by a Notified Body or an association of Notified Bodies (e.g. TEAM-NB, NBCG-Med).

This Position Paper shall address exclusively those published documents which:

- Interpret the respective Regulation without having a legally binding effect, or
- Implement the respective Regulation, and
- Do not establish a legally binding transition or implementation period,

but

- Are directed to economic operators or have a direct or indirect effect on them and their ability or their obligations to comply with the Regulations,
- Especially if they have impact on:
    - the conformity assessment of devices,
    - pre- or post-certification compliance,
    - the validity or content of certificates and declarations of conformity,
    - format and content of standardised documents like ad hoc and recurrent reports and records as formalised in the Regulations or any of their related documents, e.g. MIR, SSCP, PSUR, implant card and the like
    - specifications in the context of UDI and EUDAMED, e.g. business rules, data dictionary, and the like

- clinical investigations, their application for approval and execution, reporting, etc.
- vigilance and post-market surveillance,

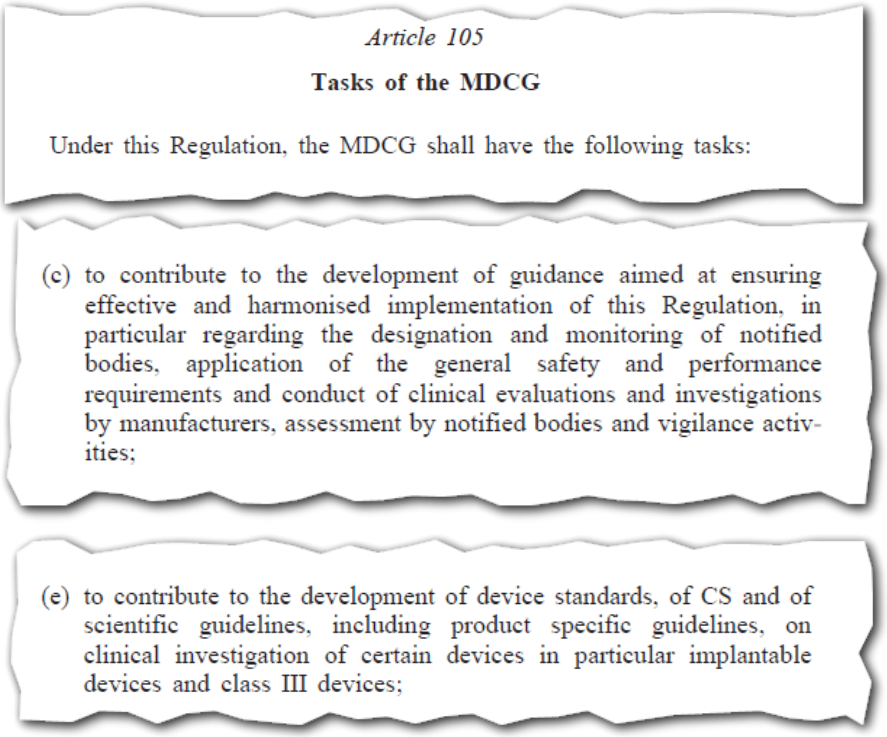
or have similar effects.

At the time of writing of this Position Paper this is mainly true for the MDCG endorsed documents. However, this Position Paper shall not be limited to these documents, but to all documents which meet the afore listed inclusion criteria.

Background

This section shall serve as a presentation of the legal role of guidance in the Regulations. The following presentation shall focus on "guidance documents endorsed by the MDCG" as the most distinct and important types of documents within the scope of this Position Paper, but this shall not exclude any other guidance, guideline or best practice document.

The Medical Devices Coordination Group ("MDCG") is established by MDR Article 103 / IVDR Article 98 and consists of representatives of each Member State. MDR Article 105 / IVDR Article 99 provides for a list of tasks of the MDCG, among which Article 105 (c) and (e) / IVDR Article 99 (c) and (e) correlate well to the afore mentioned documents.



Article 105

Tasks of the MDCG

Under this Regulation, the MDCG shall have the following tasks:

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities;

(e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable devices and class III devices;

The European Commission has published a steady stream of MDCG documents (all of which are considered "MDCG-endorsed"):

Year	2018	2019	2020	2021
Number of MDR / IVDR MDCG-endorsed documents published	8	16	18	28

The count does not include any specific COVID notice / guidance documents or refreshed NBOG best practice guidance, or other document published by the European Commission on their webpage: https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

All known MDCG-endorsed documents bear on the front page the following disclaimer:
"Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law."
In the MDCG document 2019-6 of June 2019 the Conformity Assessment Bodies (Notified Bodies are considered a subset of the CABs) are instructed in point I.1 regarding "guidance documents":

I. ORGANISATIONAL AND GENERAL REQUIREMENTS

I.1. Are CABs obliged to follow guidance endorsed by the Medical Devices Coordination Group (MDCG)?

Guidance documents are by definition not compulsory. However, all guidance documents endorsed by the MDCG reflect the interpretation of the EU law jointly agreed by the authorities which are in charge of interpreting and applying the EU law. Hence notified bodies should be encouraged to apply these guidance documents (also taking into consideration Section 1.6.2 of Annex VII to the MDR/IVDR[1]). Furthermore, it is to be noticed that the European Court of Justice often refers to guidance documents when developing its rulings. Hence Notified Bodies have an interest, also in terms of liability risk, to follow that guidance.

Section 1.6.2 of Annex VII of the Regulations specifically reflects requirements to be considered by Notified Bodies:

Annex VII: Requirements to be met by Notified Bodies

1. Organisational and General Requirements

…

1.6. Participation in coordination activities

…

1.6.2. The notified body shall take into consideration guidance and best practice documents.

For the purpose of this Position Paper there seems to be a more specific provision in the Regulations:

Annex VII: Requirements to be met by Notified Bodies

…

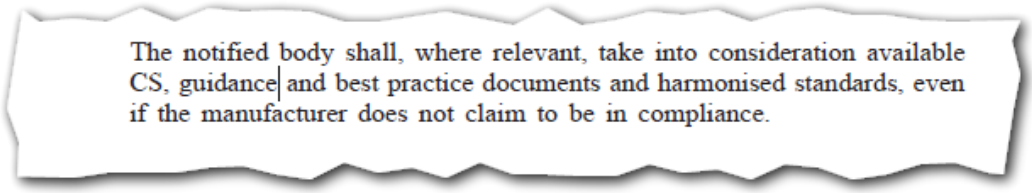
4. Process Requirements

…

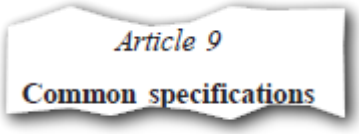
4.5. Conformity assessment activities

4.5.1. General

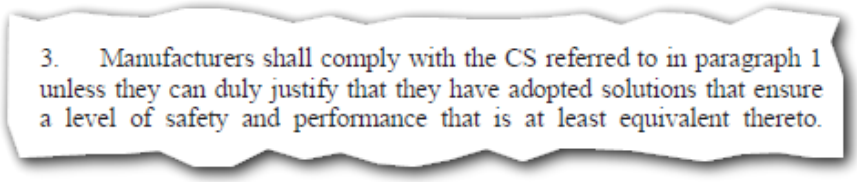
…

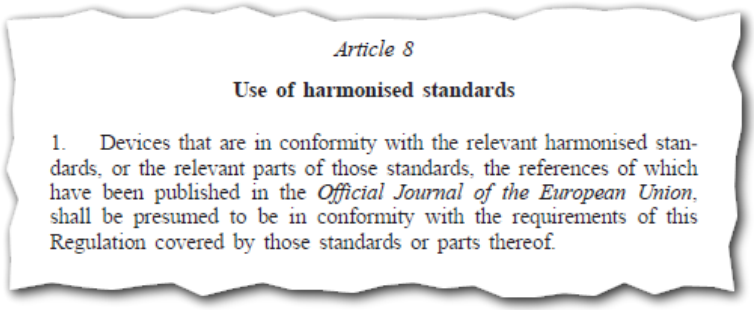

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

As a result, Notified Bodies have to consider relevant guidance documents during conformity assessment. In that regard, Annex VII, Section 4.5.1. equally lists Common Specifications, Best Practice Documents and Harmonised Standards. Unfortunately, the provision does not spell out any transitional or implementing timing for guidance documents which – in practice – may lead to their immediate consideration.
The following quotes shall give connecting views on how the MDR interprets the "taking into consideration" regarding Common Specification and Harmonised Standards:


Article 9

Common specifications


3. Manufacturers shall comply with the CS referred to in paragraph 1 unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.


Article 8

Use of harmonised standards

1. Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The use of Common Specifications (CS) - if available - is considered the preferred option but manufacturers may choose and duly justify adopting other solutions to achieve at least an equivalent level of safety and performance.

Slightly different is the view on Harmonised Standards which offer the privilege of presumption of conformity but remain as such voluntary as a method to demonstrate conformity with the General Safety and Performance Requirements as set out in Annex I of either Regulation (consult guidance document MDCG 2021-5 Section 2.2 or the "Blue Guide", 2016/C 272/01, Section 4.1.2.1 3rd bullet). Nonetheless, if alternate solutions have been chosen by a manufacturer, a justification may be required since Harmonised Standards are considered to represent the State of the Art.

The wording in MDR Annex VI, Section 4.5.1 "even if the manufacturer does not claim to be in compliance" allows the general interpretation that the compliance with CS, guidance, best practice documents and harmonised standards is not compulsory.

Challenges

The purpose of most of the above documents is to provide interpretation or implementation of a legal requirement of the Regulations. Since the legal requirements exist from the date of entry into force of the Regulations and have been interpreted as being applicable from that date, the legislators claim that a guidance cannot allow for a transition period or application date for the contained interpretation. Therefore, industry understands that such documents do not have a date or a period from when to apply the requirements of a guidance document.

However, it should be noted that the interpretation of the Regulations given by the guidance document may result in competing or conflicting views. The interpretation may also change over time due to experience with applying the Regulation or the circumstances of its application. In addition, the application, placing on the market or commercialisation of new devices may need new interpretation within the Regulation in force, where appropriate solutions were not anticipated at the time of drafting the Regulations. For example, guidance documents as an interpretation of the Regulation may be appropriate for some categories of device but may be or become completely inappropriate for other categories. It should also be mentioned, that over time Regulations may be amended or corrected, and new guidance documents may be published leaving previously published guidance documents outdated, no longer applicable, conflicting or simply incorrect.
Moreover, a differentiation needs to be made between a device which is in a conformity assessment process and not yet CE-marked and a device which is already legally placed on the market. A guidance document may even have disruptive consequences on the technical or clinical development of a device in its early or more importantly in later stages; it may jeopardise the investment into the development of a new device which was designed with correct interpretation of the current understanding of the requirements of the Regulations.

This raises the question to the concerned stakeholders of when to apply the content of a guidance. It appears that the general assumption by Notified Bodies and Competent Authorities is to comply with such a guidance document at the date of its publication. However, it is unrealistic to transfer any newly established views of a requirement into practice without a transition period that is proportionate to the significance and impact of the change. Request for immediate consideration of a guidance document is not justified unless there is a need to address issues of immediate patient safety or health emergencies.

Guidance 2019-6 of June 2019 in point I.1 suggests that Notified Bodies should apply guidance documents, especially MDCG endorsed guidance documents, which represent interpretations of the Regulations by agreement of the authorities (at least a majority of authorities). Moreover, the text is warning Notified Bodies that non-application of the MDCG endorsed guidance threatens the Notified Body with liability risks. Thus, this leads Notified Bodies to apply such a guidance document almost immediately. At the same time Notified Bodies need to introduce the new guidance document into their quality management systems, which may go beyond adding a simple reference and change their established processes, leading to training of personnel.

The unexpected issuance of a guidance document, the immediate and therefore sometimes unexpected application of a guidance document – especially if no stakeholder involvement took place prior to publication - may cause delays during the conformity assessment, part of which may need to be repeated or new requirements applied. In a worst-case scenario the existing certification of a device may be threatened. Consequently, delays on the certification and market availability of the device are to be expected. Existing documents, materials or product may become obsolete. In addition, invalidating an existing certification may have even more severe consequences.

While industry is committed to deliver safe and performing devices and complying with applicable laws and Regulations, newly arising interpretations of legal requirements should not put the supply of CE-marked medical devices onto the market and the support of patients and healthcare systems at risk, as long as safety and performance of the devices are not compromised.

Position

MedTech Europe has developed, appropriately reviewed and released the following position on the appropriate timing for the consideration of guidance documents as discussed above:

1. Industry agrees that “guidance”, “guidelines” or “best practice documents” and especially “guidance documents endorsed by the MDCG” are important and welcomed interpretations of the Regulations. Whilst helpful and useful, these documents are not legally binding. They may also result in competing or conflicting views and may change over time or due to experience or the circumstances of application.
   Industry calls for acknowledgement that guidance documents should be taken into consideration in varying degrees to devices and device categories, roles (e.g. Economic Operators), circumstances and that appropriate flexibility is necessary as long as the overall goal is respected.

2. Industry calls on the European Commission, the MDCG, the Member States or any subgroup to involve industry - as directly or indirectly as an addressed stakeholder - early in the generation of such guidance documents. A constructive discussion between the stakeholders is the basis for a widely understood and accepted guidance document and may lead to earlier adoption. The time between the first discussion and the publication of a guidance document is valuable preparation time for industry and could prevent delays in patient access to the device.

3. Industry calls for recognition from the COM, Notified Bodies and Competent Authorities that any immediate consideration of the content of guidance documents is unrealistic because changes take time and effort to be implemented. Continuous availability of devices is a key goal for industry to serve patients and the healthcare system. Unless safety and performance of a device is impacted in way that it poses undue risk to patients or users, the continuous availability of devices should be a priority.

4. The Regulations call on the Notified Bodies to consider Common Specifications, guidance, best practices documents and Harmonised Standards during the conformity assessment. The provision in Annex VII, Section 4.5 lists various documents that, where relevant shall be taken into consideration. As stipulated in the Regulations, Common Specifications and Harmonised Standards do not require mandatory application but the manufacturer is free to adopt duly justified solutions which ensure at least an equivalent level of safety and performance. Industry understands and that the Commission has agreed that the same is true for guidance documents, including guidance documents endorsed by the MDCG.

5. During conformity assessment processes, the burden to introduce new unplanned interpretation of the Regulation into the assessment should be minimised and delays to complete the conformity assessment should be avoided. Especially administrative requirements such as using a certain form, new EMDN product codes or the like do not justify any delays in conformity assessment and the timely availability of the device to patients and healthcare systems.

6. If during a conformity assessment a new guidance document is published where the Notified Body believes that consideration is required, it should ask the manufacturer to evaluate such new interpretation for applicability, propose solutions and timelines for implementation of such solutions. The Notified Body and the manufacturer should discuss and agree on an implementation plan, which shall allow timely and continuous availability of the device. The related issuance of a certificate may be connected to the condition of timely execution of the implementation plan which would be monitored by the Notified Body via surveillance activities.

7. Since the Regulations do not contain a provision from when guidance documents have to be considered by Notified Bodies after completion of the conformity assessment, industry proposes that newly published guidance documents are considered at the earliest at the time of next periodic re-assessment. Due to the nature of guidance documents which shall not bring changes to the requirements of the Regulations, suspension or withdrawal of a certificate per MDR Art. 56.4/IVDR Art. 51.4 should be considered only in the event that the conformity to the requirements of the Regulations is not met. The

principles of proportionality and the time granted to review and consider the new interpretation of the Regulations at the time of re-assessment shall avoid unavailability of the device to patients and healthcare systems, unless safety and performance are concerned.

In the case of devices, which do not undergo a Notified Body conformity assessment, manufacturers should identify in the same way an implementation plan that does not compromise product safety and performance.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.

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