

# Medical Device Regulation – One Year to Go

## COCIR Recommendations

### 1. Introduction

The medical device sector in Europe has less than one year until 26 May 2020, the Date of Application of the Medical Device Regulation (MDR - 745/2017). Six months ago, in November 2018, COCIR published a half-time assessment<sup>1</sup>. Unfortunately, the updated assessment (see Annex) shows that very little progress has been made in the implementation of the Regulation. Our members have invested considerable resources to be prepared for the MDR, but only as far as possible considering essential guidance and information is still missing.

The European Commission and member states will take stock of the implementation of the MDR in the upcoming meetings of the Employment, Social Policy, Health and Consumer Affairs Council and Medical Device Coordination Group. Here we point out some urgent challenges and offer concrete recommendations for their discussions.

While this statement focusses on the availability and capacity of Notified Bodies and the sustainability of the grace period, many other essential elements of the Regulation, including necessary guidance, are also underdeveloped or missing. These include the timely set-up of Eudamed, clear guidance on assignment of UDI, clinical evaluation & investigations, post-market surveillance & vigilance, and the obligations of different economic operators. In addition, we underline once again that there will likely be no Harmonised Standards available by the Date of Application. The impact of (almost) no harmonised standards on European market access for medical devices is outlined in our dedicated position paper<sup>2</sup>.

### 2. Availability and capacity of Notified Bodies

To date, only two Notified Bodies (BSI UK and TÜV SÜD) have been designated under the MDR. There is no indication that a significant number of Notified Bodies will be designated in the next months. That is by far not enough to accommodate the demand of medical device manufacturers.

***Recommendation:*** Limit the initial certification to the Quality Management System (QMS) and a sample of one device per device group for class IIa and class IIb devices at initial MDR certification assessment. In addition, the European Union's participation in the IMDRF's MDSAP programme and acceptance of MDSAP certificates would relieve Notified Body capacity.

***Challenges for manufacturers of class I software:*** In its FAQ on the transitional provisions, CAMD clarifies that class I devices cannot use the grace period because these "self-declared devices" lack a valid (MDD) Notified Body certificate. This applies to all class I devices under the Directives. Especially complicated is the situation for devices that are up-classified under the MDR. All these devices, if their manufacturers want them to remain on the market, will have to be certified and thus need Notified Body capacity where that is not the case prior to May 2020.

Due to the upcoming interpretation of classification rule 11 in the MDR, the above also applies to most class I software, as it will be up-classified to class IIa or higher. In practice, this means self-declaration will become very rare for software products that qualify as medical device.

***Recommendation:*** Establish a consistent, EU-wide contingency plan for manufacturers in need of a Notified Body and allow manufacturers of MDD class I devices to make use of the "grace period".

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<sup>1</sup> COCIR Half-Time Assessment:

[https://www.cocir.org/uploads/media/18064\\_COC\\_Medic\\_Regulation\\_A5\\_web.pdf](https://www.cocir.org/uploads/media/18064_COC_Medic_Regulation_A5_web.pdf)

<sup>2</sup> COCIR Position Paper on Harmonisation of Standards for Medical Devices

[https://www.cocir.org/uploads/media/COCIR\\_Position\\_on\\_Harmonisation\\_of\\_Standards\\_-\\_Final.pdf](https://www.cocir.org/uploads/media/COCIR_Position_on_Harmonisation_of_Standards_-_Final.pdf)

### 3. Use of the grace period

Article 120(3) of the Medical Device Regulation states that devices having a valid certificate issued by a Notified Body under the Medical Device Directives may be placed on the market after the Date of Application of the MDR under certain conditions, but no later than 27 May 2024. Due to the missing elements in the MDR framework and the large uncertainties in the interpretation of relevant requirements, it is even more important that manufacturers can make full use of this grace period to prevent large disruption in the supply of medical devices. However, even in Article 120 some aspects remain unclear:

#### 3.1. Interpretation of significant change

A significant change in design or intended purpose of a device after the date of application of the MDR may prevent the manufacturer from continuing to place that device on the market under Article 120 (3). The CAMD provides some guidance on the interpretation of Article 120 in their FAQ on MDR Transitional Provisions<sup>3</sup>. However, further clarity is needed for manufacturers.

***Recommendation:*** Publish specific guidance on significant change as referenced in Article 120 (3). Such guidance also needs to acknowledge that MDD certificates remain valid following changes that are unrelated to design or intended purpose of the device in question (e.g., organizational changes). COCIR has provided detailed proposals on the subject of “significant change” to regulators that we expect to be taken up.

#### 3.2. Registration of legacy devices

The European Commission has recently published the Medical Device Coordination Group’s decision on the registration of legacy devices<sup>4</sup>. Legacy devices (devices with a MDD certificate placed legally on the market after the Date of Application) will be assigned a pseudo “Eudamed DI and ID”. This change is introduced very close to the Date of Application – only little more than a year beforehand, while our members are already in the process of preparing their internal systems. Several challenges remain as some devices have already been assigned a UDI due to non-EU obligations.

***Recommendation:*** As agreed in the dedicated MDCG UDI Working Group, we would like official confirmation that the “pseudo UDI” allocation does not affect labelling or direct marking of devices. The manufacturers can keep the current UDI (if existing) on the labels, direct marking and other technical files. When existing, UDI-DI identification should be accepted to identify MDD devices in Eudamed, under provision the same UDI-DI can be used for both versions (MDD and MDR) of the same device when those versions are identical.

### 4. Conclusions

This is a critical period for the entire medical devices regulatory system. If the European Union’s ambition for medical devices are to be realised, the full regulatory framework will have to be in place and functioning. At this moment, it appears that much effort is needed to complete the framework in time. The current delays in implementation make the European Union a less attractive region for investment by medical device manufacturers, and likely increase cost for hospitals and threaten patient access.

We believe that our concrete recommendations will help to address the most urgent concerns faced by the EU regulatory system. We count on the European Commission and member states to take a pragmatic approach to ensure that healthcare delivery will not face any negative consequences from the implementation of the new regulation.

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<sup>3</sup> [https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ\\_MDR\\_180117\\_V1.0-1.pdf](https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf)

<sup>4</sup> <https://ec.europa.eu/docsroom/documents/34922?locale=en>

Annex: COCIR updated assessment of the MDR's implementation status

1. GENERAL FRAMEWORK	 <p><b>UNIQUE DEVICE IDENTIFICATION (UDI)</b></p>		<ul style="list-style-type: none"> <li>• Eight guidance documents published to date</li> <li>• Striving for convergence with global efforts at IMDRF level as far as the Regulation permits</li> <li>• Decision on nomenclature has been taken</li> </ul>
	 <p><b>EUROPEAN DATABASE FOR MEDICAL DEVICES</b></p>		<ul style="list-style-type: none"> <li>• Implementation plan published on time</li> <li>• Data dictionary for UDI &amp; Devices module published</li> <li>• Several modules so far delayed that they will not be part of first release in March 2020</li> <li>• Timing for validation of actor registration remains a concern</li> </ul>
	 <p><b>HARMONISED STANDARDS</b></p>		<ul style="list-style-type: none"> <li>• Standardisation request not yet adopted</li> <li>• List of candidate standards unclear and insufficient</li> <li>• Worsening administrative processes for harmonisation of standards</li> </ul>
	 <p><b>TRANSITIONAL PROVISIONS</b></p>		<ul style="list-style-type: none"> <li>• No clarity on interpretation of significant change according to Article 120.3 (expect development of NBOG guidance)</li> <li>• Guidance for legacy devices (UDI obligation, sufficient clinical evidence etc.) delayed or requires more clarity</li> </ul>
	 <p><b>CLINICAL EVALUATION AND INVESTIGATIONS</b></p>		<ul style="list-style-type: none"> <li>• Lack of stakeholder consultation</li> <li>• Guidance on sufficient clinical evidence and equivalence for higher-risk legacy devices severely delayed</li> <li>• No plans as yet for guidance for lower-risk devices</li> </ul>
2. PRE-MARKET OBLIGATIONS	 <p><b>MEDICAL SOFTWARE</b></p>		<ul style="list-style-type: none"> <li>• Guidance on qualification and classification delayed (publication of classification guidance expected in June 2019)</li> <li>• Guidance on clinical evaluation of software progressing well</li> </ul>
3. PMS	 <p><b>POST MARKET SURVEILLANCE AND VIGILANCE</b></p>		<ul style="list-style-type: none"> <li>• Field Safety Notice and MIR form published<sup>4</sup></li> <li>• Development of several guidance documents and templates (e.g. PSUR) delayed</li> <li>• No clarity on possible delegation of activities between Economic Operators (e.g. pre-evaluation of incidents by distributors)</li> </ul>
4. RELEVANT ACTORS	 <p><b>ECONOMIC OPERATORS</b></p>		<ul style="list-style-type: none"> <li>• Uncertainty on sub-contracting of verification activities between different economic operators</li> <li>• No clarity on use of sampling methods by importers</li> <li>• Original Equipment Manufacturer/Own Brand Labeller obligations under discussion</li> </ul>
	 <p><b>NOTIFIED BODIES</b></p>		<ul style="list-style-type: none"> <li>• Only 2 Notified Bodies designated by May 2019</li> <li>• Significant increase in demand expected for Notified Bodies, particularly for software and apps, due to changes to classification rules</li> <li>• Uncertainty on MDR interpretation among Notified Bodies</li> </ul>