Medical devices regulations

Considerations for ESMAC members

The purpose of this document is to provide ESMAC members with general information about the Medical Devices Regulations (MDR) which came into force within the EU on 26 May 2021 [1-4]. Our focus is to provide condensed information and alert ESMAC members to how the current MDR affects gait laboratories. Labs in the UK are encouraged to also refer to *MDR: FACTSHEET & POSITION STATEMENT by CMAS* [5] and to *SOFTWARE AND AI AS A MEDICAL DEVICE CHANGE PROGRAMME* [6].

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1. Introduction

The **Competent Authorities for Medical Devices (CAMD)** Executive Group recommended the establishment of a medical devices (MDR) and in vitro diagnostic medical devices (IVDR) implementation taskforce to facilitate collaboration and cooperation within the medical devices network during the implementation phase of the new Regulations (2017-2021) [1-4, 7-12].
The 26th May 2021 marks the full application of the new EU Regulation on Medical Devices (MDR. Regulation (EU) 2017/745).
"*The MDR represents a significant update to the existing medical device Directives which have been in place for 30 years. The MDR aims to strengthen and improve the regulatory system for medical devices in Europe to ensure that medical devices are safe and perform as intended over their lifetime. It also aims to ensure that innovation and development of new technologies is supported in Europe to afford patients and health systems new diagnostic and therapeutic options*.[1]"

For those who are not familiar with MDR, before proceeding with the description of the implications of the new MDR for clinical gait analysis laboratories, it is worth mentioning that the main purposes of MDR are as follows [1]:

A. to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators;
B. to enable unique identification of devices within the internal market and to facilitate their traceability;
C. to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with MDR obligations [1];
D. to enable manufacturers to comply with the information obligations laid down in the MDR [1] ;
E. to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them.

Consequently, there is a need to identify the users and contact points of the national competent authorities, notified bodies, sponsors, economic operators, investigators and the persons responsible for regulatory compliance.

2. Medical devices according to NEW MDR [1-3]

A. A **Medical Device** is defined by the MDR as any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

B. An '**Accessory for a medical device**' is defined as an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose. It is possible that an app that is connected to a device that measures vital data is qualified as an accessory for a medical device.

C. **It is important to note that not all software used within healthcare is regarded as a medical device**. **Decisive is the intended purpose and functionality of the software/app.**

D. One needs to distinguish between **software for medical purposes and software for general purposes**.
    a. **Software** which is intended to process, analyse, create or modify medical information may be qualified as a **medical device software** (i.e. software used to generate a gait report) if the creation or modification of that information is governed by a medical intended purpose.
    b. **Software for general purposes** (i.e. word processor or spreadsheet software) even in a healthcare setting is not a medical device.

E. **Classification**: Regarding devices that are intended to be used in combination with another device, it has to be observed that the classification rules apply separately to each of the devices (i.e. when devices are combined such as an EMG system and 3D motion capture system). It is worth mentioning that in the case of combined use of multiple devices the user is exceeding the classification obtained by the supplier and therefore using both devices outside their intended purpose and must ensure that the requirements of a Health Institution Exemption (HIE) are met. The exception is if a supplier combines two systems and undertakes the classification process.

F. **Accessories** for a medical device shall be classified in their own right separately from the device with which they are used. The same applies for software that is independent of any other device, it shall be classified in its own right. However, software, which drives a device or influences the use of a device, shall fall within the same class as the device.

3. MDR in Clinical Gait Analysis [1-5]

Laboratories subjected to EU regulations should:

A. **Ensure that their medical devices purchased after 26 May 2021 are compliant with MDR and have obtained the necessary CE certificates.**

B. Consider the requirements needed for a HIE in light of the new MDR (this will include identification, validation, restricted access to core code/process and protocols around use).

C. Consider their use of **in-house software** or that obtained from other Labs (i.e. running in Matlab, Python, OpenSim) complies with the new MDR:
   1. They are subjected to certification if they are *qualified as a medical device (i.e. the creation or modification of the information processed by the software is governed by a medical intended purpose)*
   2. The new medical device classification rules may affect the classification of motion analysis systems. The most important change for gait analysis is that **software shall also be deemed to be an active device**. As a result, any (stand-alone) software intended to provide information used for diagnostic or therapeutic purposes is now classified as IIa or IIb (it is worth mentioning that IIa classification seems insufficient when we use our data to make surgical recommendations). However, in some cases the data is interpreted alongside clinical and other info and therefore the recommendation is that of the user (not the software).
   3. The new classification creates a distinction between software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes which is classified as Class IIa, except if such decisions have an impact that may cause: a surgical intervention, in which case it is classified as Class IIb (see MDR, Chapter III, section 6.3, Rule 11). It is however unclear if deriving surgical recommendations from motion capture data would constitute an “off label use” i.e. exceeding the classification of the motion capture software.
   4. Several suppliers of Motion Capture systems and related hardware (i.e. force platforms, electromyographic systems, plantar pressure systems) have obtained Class IIa classification. *In some cases suppliers are taking advantage of the Eudamed derogations (up to two years) around registration for devices being placed on the market for a limited period after the transition period under a certificate issued in line with the Directives [1-4].*

5. Devices that are manufactured or modified and used within health institutions shall be considered as “having been put into service”. The requirements in the MDR/IVDR shall not apply to these devices provided that certain conditions are met, including but not limited to [1-4]:
    i. the products meet the relevant General Safety and Performance Requirements
    ii. there is a justification for applying the exemption (no equivalent device on the market)
    iii. technical documentation is in place
    iv. information is made available to competent authorities on request
    v. a declaration with certain details is made publicly available
    vi. the user reviews experience gained from clinical use of the devices and takes all necessary corrective actions

    Important note: Cost of available equivalent devices would not generally be considered to be a valid justification for developing and using own software. Also, the extent/detail of the justification should be proportionate to the risks of the device.
6. Gait labs subject to MDR must ensure they have met the criteria for a health institution exemption (HIE) for any devices, including software/code, that were obtained from a third party (supplier, other gait lab, research lab) that are used in the assessment process and are not appropriately classified as a medical device or have lost its classification due to off label use.

4. Conclusion

By considering that the 26th May 2021 marked the full application of the new EU MDR, it is recommended that all ESMAC laboratories consider the implications of the EU MDR.
Particular attention should be paid to the classification of the instrumentations in use at the Gait Lab (i.e. motion capture, force platform, electromyographic systems, plantar pressure systems, IMU). Class IIa is required, although some suppliers are taking advantage of the "*transition period" of two years.*
The most important change for gait analysis is that Software shall also be deemed an active device. As a result, any (stand-alone) software intended to provide information used for diagnostic or therapeutic purposes is now classified as IIa or IIb. Therefore, every Gait Lab should consider ensuring that their in-house software complies with the new MDR. As software can be a medical device, this has an impact on the sharing of software between gait labs (it is worth mentioning that any entity that shares software with another legal entity is a medical device supplier, even if shared free of charge, and therefore would need to obtain a CE mark etc). Any lab using such software MUST assume responsibility for this software and ensure the requirements for a HIE are met.

Disclaimer
This document is NOT a legal text. The content is the opinion of those involved in the ESMAC board. Each member laboratory must ensure that they are compliant with their own local regulations with respect to software development and sharing, the purchasing and maintenance of medical equipment and the correct use of that equipment.

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References

[1]. MDR. Regulation (EU) 2017/745. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=IT

[2]. MDR-IVDR CAMD Implementation Taskforce

[3]. Guidance on standardisation for medical devices. https://ec.europa.eu/health/system/files/2021-04/md_mdcg_2021_5_en_0.pdf

4]. MDR, 2021 may 26th, Date of Application is now ! - CAMD

[5]. MDR: FACTSHEET & POSITION STATEMENT. Clinical Movement Analysis Society UK & Ireland (CMAS)- https://cmasuki.org/news/mdr_fact_position_statement/

[6] https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme).

[7]. https://ec.europa.eu/eip/ageing/file/3612/download_en%3Ftoken=_QoQUjGh

[8]. Active and Healthy Living in the Digital World | Futurium

[9]. Critical Review of European Health-Economic Guidelines for the Health Technology Assessment of Medical Devices (2019): https://doi.org/10.3389/fmed.2019.00278

[10]. MDCG 2018-1 v3 Guidance on BASIC UDI-DI and changes to UDI-DI, European Commission (2020): https://ec.europa.eu/docsroom/documents/40322

[11]. Unique Device Identification (UDI) System under the EU Medical Device Regulations, European Commission (2017) https://ec.europa.eu/docsroom/documents/36664/attachments/1/translations/en/renditions/native

[12]. Medical Devices-Sector, European Commission: https://ec.europa.eu/growth/sectors/medical-devices_en