MDR:
FACTSHEET & POSITION STATEMENT

Clinical Movement Analysis Society UK & Ireland (CMAS)

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Approved by CMAS MDR Subcommittee, CMAS Main And Standards Committee Chairs

Executive Summary

The Clinical Movement Analysis Society (CMAS) is registered charity and company limited by guarantee. It is a peer formed network of clinical movement analysis laboratories located in the United Kingdom (GB & NI) and the Republic of Ireland. As of April 2021, CMAS is comprised of 14 affiliated laboratories and associated individual members. CMAS is engaged in education, peer support and the setting and auditing of standards for clinical movement analysis. The standards function is performed via the CMAS Standards Committee while the overall operation of the society is overseen by the CMAS Main Committee.

2021 brings some specific challenges with respect to how CMAS operates. Until this year, all CMAS laboratories functioned within a European Union regulatory framework. With the UK exiting the EU on 31 December 2020, this is no longer the case. One immediate point of divergence relates to the regulation of medical devices, including equipment and software related to clinical gait analysis, sold in the EU and UK markets. The EU Medical Devices Regulation (MDR), replaces the previous Medical Devices Directive (MDD), and comes into force within the EU on 26 May 2021. The UK market will continue to be regulated using the framework of the existing MDD. The exception is Northern Ireland, where, due to the provisions of the Northern Ireland Protocol, medical devices sold within NI will be subject to EU regulations but may also have UK approval as a secondary measure.

This document seeks to provide clarity to members and member laboratories regarding the regulatory implications for CMAS in 2021.

It is recommended that all CMAS laboratories consider the implications of the EU MDR, specifically:

1. Laboratories subject to EU regulations should:
    a. Ensure the suppliers of medical devices purchased after 26 May 2021 are compliant with MDR and have obtained the necessary CE certificates.
    b. Consider their use of in-house software or non-intended use of supplied medical devices and implement the requirements needed for a Health Institution Exemption.
2. Laboratories not subject to EU regulations should:
    a. Make themselves familiar with this document and be aware of any impending changes in UK medical devices regulations (expected to become active in July 2023).
    b. Be aware of the possible implication of sharing their ‘in-house’ software with laboratories based in the EU regulatory zone.

Disclaimer

This document is NOT a legal text. The content is the opinion of those involved at a committee level in CMAS. Each member laboratory much 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.

MDR Subcommittee: Colm Daly (CMAS Standards Committee Chair), Bart Koning (CMAS Secretary), Martin Molloy, Damien Kiernan (CMAS Vice Chair), Matt Thornton (CMAS Main Committee Member)

Contents

1. Medical devices in clinical gait analysis

1.1 Introduction

This introduction discusses elements of the law(s) around medical devices most relevant for clinical gait labs and impact of new EU legislation that have become fully applicable on 26 May 2021. The document focusses on the new, stricter EU legislation, much of what is described below already applies with current EU (and UK) legislation.

A device is classed as a medical device when the intended purpose is (incomplete list below):

- 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

Any manufacturer must comply with the Medical Device Directive (MDD 2007, n.d.) (England, Wales and Scotland) and the Medical Device Regulations (MDR 2017, n.d.) (Northern Ireland and Ireland) when a medical device is:

- 'made available on the market': "any supply of a device, other than an investigational device, for distribution, consumption or use […] in the course of a commercial activity, whether in return for payment or free of charge"
- 'put into service': "the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use"

As such, motion analysis hardware and software does not necessarily have to be classed as a medical device when it is made available on the market. This is only required when its intended purpose, as declared by the manufacturer, is in line with that of a medical device.

Another important aspect to be aware of is the intended use of certified medical devices. Certification comes with clear instructions of intended use, as these are the conditions under which the medical devices will have been verified, validated, and thus certified. Not adhering to this intended use is often referred to 'off-label use'. Off-label use could be the result of merging certified systems (MDR HEI, n.d.) as is often the case in movement analysis e.g. the combination of an EMG system with a 3D motion capture system.

In the context of a clinical gait analysis, hardware and software used within the lab to facilitate clinical gait analysis should be considered as a medical device "having been put into service". Therefore, the lab must take full responsibility for hardware or software use and outcomes when these devices are:

- Not certified as a medical device as it was made available on the market.
- Used off-label.
- Developed or manufactured in-house.

1.2 Key changes with the MDR

There have been many changes for the MDR, but the text below focusses on what we believe are the two key changes relevant to the day-to-day practice of a clinical gait lab:

- Stricter classification rules, with a focus on software.
- Stricter rules for Health Institution Exemption (HIE) for EU regulated labs (including Northern Ireland and Republic of Ireland).

1.2.1 Classification rules (Annex VIII)

The new medical device classifications 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.

It is noted that the new classification also 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 our understanding that the suppliers of Motion Capture systems are/have obtained Class IIa classification. It is therefore somewhat unclear if deriving surgical recommendations from motion capture data would constitute an 'off label' use.

1.2.2 Health Institution Exemption (HIE)

Regulations regarding in-house manufacture have become stricter. Guidance documents have been made available to comply with MDR (MDR HEI, n.d.).

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:

- … the products meet the relevant General Safety and Performance Requirements
- … there is an appropriate quality system in place
- … there is a justification for applying the exemption (no equivalent device on the market)
- … technical documentation is in place
- … information is made available to competent authorities on request
- … a declaration with certain details is made publicly available
- … reviews experience gained from clinical use of the devices and takes all necessary corrective actions

Important to note: Cost of available equivalent devices would not generally be considered to be a valid justification and the extent/detail of the justification should be proportionate to the risks of the device. (MDR HEI, n.d.) (MHRA MDR One Pager, n.d.)

1.2.3 Healthcare Institution Exemption for acquired items

Gait labs subject to MDR (those based in Northern Ireland and Ireland) 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.

For example, the supplier documentation may only state how to collect data using their own proprietary software (intended use). Collecting data using third-party software to enable synchronised measurement

could fall outside of the manufacturers 'intended use' and may void the medical device classification. If that is the case, the need for synchronised measurements can be used as a justification in the HIE. The technical documentation that accompanies the HIE could include verification of data quality (original intended use), verification of system synchronisation (expanded intended use) as well as over-all validation of the combined system in clinical practice. Labs subject to EU regulation are advised to ensure all aspects of section 1.2.2 above are met.

1.2.4 Classification and software

Gait labs (particularly those subject to EU regulations) are advised to thoroughly review their own software, using the decision tree and examples provided by the appropriate software guidance documents (MDR Software guidance, n.d.). This could range from hardware configurations settings, biomechanical modelling, data post-processing to data-compression methods applied. Despite the software guidance documents, there is much debate on what software should be classified as a medical device and what constitutes stand-alone software (Stronach, 2020).

For example, any of the following could be identified as "Software driving or influencing the use of a medical device" (MDR Software guidance, n.d.) or as a Medical Device Software (MDSW) in itself:

- modification of processing parameters (e.g. filter settings);
- modification of the default models (e.g. hip joint centre definitions);
- application alternative biomechanical models not supplied/certified by the manufacturer;
- custom post-processing (e.g. calculation of GPS in and Excel template);
- non-lossless compression of videos (with or without ground reaction vector).

The purpose of this document is not to define what is or is not Medical Device Software in the context of gait analysis but to encourage gait labs to critically appraise their own software. Any software identified as a medical device should be defined by the scope of the medical device classification provided by the manufacturer. Any use outside of this scope will be require a HIE.

The Health Institution Exemption guidance documents point out the requirements for proper documentation of the manufacturing process and surveillance (MDR HEI, n.d.). This requires for proper documentation of the software development life cycle, such as:

- Planning
- Development or Design
- Verification (of elements in the software)
- Validation (of the intended use)
- Release
- Maintenance

The last element (maintenance) should clearly describe the surveillance of the software once it is implemented in standard clinical practice and could include details of how the following aspects are addressed:

- Reporting/monitoring
- Bug fixing
- Upgrading/(re)developing
- Decommissioning

Labs subject to EU regulations should refer to section 1.2.2 of this document as a guide to ensure in-house software is compliant with MDR requirements.

1.2.5 Sharing of software

Full MDR compliance, including CE-marking, is required for any medical device that is 'placed on the market'. As software can be a medical device, this could have an impact on the sharing of software between gait labs. There are two elements in this that cause debate and we will address both sides of these arguments for each:

- Would the shared software be classified as a medical device?
    - Yes, because the gait lab is sharing software that it uses as a medical device.
    - No, as long as the software, such as a biomechanical model, itself does not serve a medical purpose.
- Does sharing software between gait labs constitute as making this software "available on the market'"?
    - Yes, because the software leaves the legal entity when it is shared and thus it is placed on the market.
    - No, as long are there is no "commercial activity" in relation to sharing this software. This implies that the receiving lab assumes all responsibility for the software, as if it was their own.

It should be noted that any lab sharing software with a lab based in the EU regulatory zone, where the software is deemed to be a medical device and where the sharing is deemed to be 'making it available on the market' may be considered a supplier for EU regulatory purposes and therefore subject to all the requirements of a supplier of a medical device on the EU market.

Gait labs should exercise caution when sharing any software and, in response to the two elements discussed above, are advised to:

- Refrain from any medical claims, for example by using clear disclaimers in the source code and other correspondence.
- Avoid any suggestion relating to receiving financial benefit or other commercial gain in relation to sharing this software.

Any gait lab receiving software is advised to treat is as their own and, if subject to EU regulations, ensure they have met the requirements of a HIE, including all the verification, validation, documentation and other responsibilities that go with it. As such, it is not advisable to receive any software without the complete source code as this would render verification of individual parts impossible.

Please note, although sharing in-house manufactured hardware is less likely in the context of clinical gait analysis, any of the arguments above could also be applied to any in-house manufactured hardware.

1.3 UK Markings

The Medical and Health Regulatory Authority MHRA will continue to oversee regulations of medical devices placed on the marked on the island of Britain and have a capacity to review devices in Northern Ireland on request. From July 2023, all devices placed on the UK market must have a UKCA mark. Until that date, products will continue to have a CE mark and may also have a UKCA. Products placed on the

Northern Ireland market will require a CE mark (and be classified under MDR) and may also have a UKNI mark if desired.

1.4 Final considerations

- To identify off-label use, it is recommended to investigate the device classification, its scope and intended use in collaboration with the manufacturers. Discuss in detail how their medical device is used in your service, as this is likely to be different in each lab.
- In general, output resulting from medical devices in gait analysis are never used in isolation. It is always combined with other vital sources of information such as a clinical examination and subjective assessment. Also, interpretation of the data of is generally not automated and based on human assessors. These aspects can be included in risk assessments related to the medical devices in a lab.
- The regulations often refer to terms like 'appropriate', for example with regards to the requirement of an appropriate Quality Management System when applying for HEI. Certification to international standards, such as "ISO 13485:2016 - Medical Device Quality Systems" or "ISO/IEC 12207:2008 - Systems and software engineering" are beneficial, but not strictly required. However, gait labs are advised to look at the key elements of these standards.

2. CMAS Standards

The Medical Devices Regulation will only have a minor impact on the CMAS Standards and Checklists. As various parts of the MDR become active the Standards and associated checklists will change as follows:

Existing text

- Standard
    - Resources and Facilities
        - Section 2: Equipment
            - Subsection 2: All equipment classed as a medical device and manufactured after 1998 should be CE marked.
- Checklist:
    - RF29.2/29.2: Is there evidence of CE marking if it is a medical device manufactured after 1998.

Proposed changes:

Requirements specific to the region that the lab is located will need to be included. For medical devices manufactured between 1998 and 2021 the CE mark requirement will remain and will continue to be required for devices purchased in the Republic of Ireland and Northern Ireland. There will be a requirement to produce evidence of UKCA marking for medical devices purchased in Britain from July 2023.

CMAS will undertake a review of standards relating to in-house development of software and make any necessary changes related to quality assurance practices for such devices. This will take into account the regulatory differences between the Republic of Ireland, Northern Ireland and Britain. This process will be undertaken with full engagement with the CMAS membership as any changes will likely require a vote at the CMAS 2022 or 2023 AGM as a major amendment to the standards.

3. Recommendations

It is recommended that all CMAS laboratories consider the implications of the EU MDR, specifically:

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    b. Be aware of the possible implication of sharing their 'in-house' software with laboratories based in the EU regulatory zone.

4. References

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