

HPRA MEDICAL DEVICES

NEWSLETTER

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Consultation launched on Draft MDCG MDR Classification Guidance

On 1 April 2020, DG Santé in the European Commission launched an open consultation on the Draft MDCG guidance document for classification under the MDR. This open consultation period invites all Borderline & Classification Working Group stakeholders to provide feedback on the draft guidance and the opportunity to become involved in the development process by submitting their views. Stakeholders participating in this Working Group should have received the documents and instructions for providing feedback through CIRCABC. The consultation period is four weeks and comments are expected by the end of April.

HPRA UPDATES

COVID-19: Medical Devices Update

Overview of Testing Strategy

As the regulator for medical devices and *in vitro* diagnostic medical devices (IVDs) in Ireland, the HPRA is a member of the National Public Health Emergency Team (NPHE) which co-ordinates the management of and response to COVID-19 in Ireland.

The HPRA wishes to advise that currently all testing for COVID-19 in Ireland is under the direction of the NPHE and is conducted in the National Virus Reference Laboratory (NVRL) and in a number of hospital diagnostic laboratories and other designated laboratories. All samples are currently taken by healthcare professionals in a community test centre or in the patient's home.

Any future changes to the national testing strategy as directed by NPHE will also be communicated to healthcare professionals, members of the public and industry stakeholders.

The current testing strategy in Ireland, based on expert advice, involves laboratory-based pathogen detection using nucleic acid technology (NAT) methods (PCR). Our experts agree that serological assays currently cannot compete with molecular diagnosis, particularly in the early phase of infection. This is particularly marked in those who are immunocompromised, and in the elderly.

The HPRA would like to reiterate the importance that all testing in Ireland is aligned with this national approach and transparent to ensure that:

- test results are reported to the relevant stakeholders (for monitoring and surveillance purposes);
- contact tracing activities are initiated (where appropriate); and
- an incorrect test result does not lead to false reassurance resulting in individuals failing to seek the necessary medical help. During this time, the individual may also unknowingly spread the virus.

HPRA is aware of [falsified tests](#) for the diagnosis of COVID-19 circulating in Europe but has no evidence to date of their availability in Ireland. Falsified tests are fake or counterfeit tests that vendors pass off as real and/or certified.

Advice for Economic Operators (e.g. manufacturers, distributors, wholesalers):

- If you are considering supplying IVD tests for COVID-19 to the market in Ireland, please contact the HPRA. We can advise if the test is supported by the national testing strategy at a point in time.
- The HPRA can also advise if the test has regulatory approval for its intended purpose.
- Please forward a copy of this information notice to all relevant personnel within your organisation.
- Report any concerns/queries regarding this issue to the HPRA.

Advice for Healthcare Professionals (e.g. pharmacists, GPs):

- If you are approached in relation to IVD tests for COVID-19, we would recommend to declining such approaches. Please contact the HPRA and we can advise if the test is supported by the national testing strategy at a point in time.

Advice for Members of the Public:

- Always rely on your healthcare professional for guidance on testing for COVID-19 - do not purchase tests for COVID-19 online or from any other retailer.
- If you have any concerns regarding your health, please visit the [HSE website](#) for advice.

Please visit our [webpage](#) for up-to-date information on medical devices and COVID-19.

National Derogations for Covid-19 Critical Devices

The HPRA has developed a process for the urgent assessment of applications to use non-CE marked medical devices in Ireland, in the context of the COVID-19 emergency. The HPRA assesses these devices to determine whether the provision of non-CE marked devices is in the interest of the protection of health.

Information on how to apply for this derogation is available on our [website](#).

This process is unique to Regulatory Derogations specifically for the management of the COVID-19 pandemic.

The HPRA will conduct an initial review of the submission and will work with the consultant and manufacturer applicant to progress the application to the Management Committee for final review and decision. If you have any queries regarding this process, please contact devices@hpra.ie.

Regulation of Hand Sanitiser and Face Masks

Hand Sanitisers

The appropriate regulatory framework that applies to hand sanitiser products must be approached on a case-by-case basis. This will depend largely on the product's intended purpose, function, composition, mode of action and labelling claims. Typically, hand sanitiser products would fall within the scope of one of three pieces of legislation; the Cosmetic Regulation ((EC) 1223/2009), the Biocide Regulation ((EU) 528/2012) or the Medicinal Products Directive 2001/83/EC.

Hand sanitisers that:

- make general claims in relation to an antibacterial action or killing of germs are classified as biocides and regulated by the [Pesticides Registration and Control Division](#) in the Department of Agriculture, Food and the Marine;
- intended to clean and/or moisturise the hands whilst providing a secondary antimicrobial effect such as a soap, are classified as a cosmetic;
- contain medicinal substances and are presented as treating a disease or preventing a virus or an infection should be classed as a medicine.

Both cosmetics and medicines are regulated by the HPRA. Covid related queries on the classification of cosmetics, medicines or medical devices can be submitted to covid19@hpra.ie. Please include COVID-19 in the subject line.

If you have any queries on registration of biocidal products for hand sanitisation, please contact biocides@agriculture.gov.ie. The EU Commission has published a guidance document on the applicable regulatory framework for the placing on the EU market of hand sanitisers. This document can be found on the Commission's [website](#).

Face Masks

The regulation of face masks differs depending on the type of face mask and intended purpose of the mask. Face masks may be considered Personal Protective Equipment (PPE), Medical Devices or in some instances they can be considered both.

Personal Protective Equipment (PPE)

Face masks intended to protect the user from inhalation of hazardous substances are classified as PPE and are regulated in accordance with Regulation (EU) 2016/425. The Health and Safety Authority (HSA) is responsible for the regulation of PPE and further information on respiratory PPE is available on their [website](#).

Medical Devices

Surgical face masks that are intended to be used to protect the patient in a medical, surgical or dental setting are classified as Class I medical devices. Surgical masks that qualify as medical devices should be CE marked in accordance with the essential requirements of the Medical Devices Directive (MDD) (93/42/EEC). For any queries related to surgical face masks, please contact devices@hpra.ie.

Harmonised standards may also be used to demonstrate conformity to this Directive, for example, surgical face masks are covered by EN 14683:2019. Further information on harmonised standards is available on the [HPRA's website](#) and European Commission's [website](#).

Dual Purpose Masks

In certain instances, face masks may meet the definitions of both PPE and a medical device. These products will be considered to have a dual purpose and will fall within the scope of both the PPE Regulation and the MDD. In this scenario, Article 1(6) of the MDD would apply; the product will be regulated as a medical device and must comply with the legal requirements of the MDD. In addition, the product must meet the relevant basic health and safety requirements (BHSR) of the PPE legislation. Manufacturers should determine on a case-by-case basis which basic health and safety requirements and conformity assessment procedures are applicable to their product from the

PPE legislation, taking into account its specific intended purpose. Further information on the application of this principle can be found in the European Commission's [Interpretative Guide](#) (2009), the Commission's [Blue Guide](#), Chapter 2.2.1 and their [guidance](#) on conformity assessment procedures for PPE. In addition, the European Commission has published a [Recommendation on conformity assessment procedures](#) in the context of Covid-19.

In-House Manufacturing of *In-vitro* Diagnostic Medical Devices



Current Legislative Requirements for In-Vitro Diagnostic Medical Devices

The majority of laboratory tests used in health institutions are CE marked as *in-vitro* diagnostic medical devices (IVDs). The IVD Directive 98/79/EC (IVDD) outlines the requirements that IVD manufacturers have to meet. However, the ever-changing

diagnostic landscape brings with it many challenges including the need to adapt to emerging diseases and address patient-specific needs. From a diagnostic perspective, this can sometimes be challenging where commercially available options are limited. Recognising this need, the IVDD includes a provision for health institutions to manufacture and put into service IVDs without having to meet all of the obligations incumbent on the legal manufacturer of CE marked IVDs. This is known as the 'in-house' manufacturing exemption. It is allowed provided the IVDs are manufactured and used only within the same health institution (i.e. not transferred to another legal entity and/or placed on the market) or manufactured on a commercial scale.

The exemption is intended to facilitate health institutions in addressing specific healthcare requirements where CE marked alternatives may not be readily available, for example, in diagnosing rare diseases or managing emerging or highly mutagenic infectious agents.

Currently the exemption under the IVDD can be applied to IVDs as follows:

- IVDs that are manufactured 'in-house' and used to test patient samples from the same health institution.
- IVDs that are manufactured 'in-house' and used to test samples from external patients i.e. from a GP practice or another hospital.

Changes under the New EU IVD Regulation

The new *In-Vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR) will replace the IVDD in May 2022. This regulation significantly changes how IVDs are regulated. Alongside changes to classification, clinical evidence requirements and the notified body certification requirements there are also changes to the in-house manufacturing provisions.

Under the IVDR, IVDs which are manufactured or modified and used in-house are considered as having been 'put into service' and are within the scope of in-house manufacturing. Specific conditions have been outlined in order to qualify for a **health institution exemption**. This will impact facilities that make or modify IVDs for use within their organisation.

CE marked IVDs which are modified to meet the needs of a specific patient group, specific performance requirement or which are used for a purpose not stated by the manufacturer must meet the requirements for in-house manufactured devices under the IVDR health institution exemption.

Health institutions who make/modify and use IVDs can continue to do so after May 2022, however certain conditions and regulatory requirements will need to be met.

IVDR Regulatory Requirements Include:

Accredited to ISO 15189

Appropriate QMS is in place

IVDs are not transferred to another legal entity

GSPR requirements of IVDR are met

IVD documentation to be made available upon request (some elements must be publically available)

In summary, after May 2022 any in-house manufactured IVDs are considered as having been put into service and are within the scope of the IVDR. The health institution exemption

acts to reduce the regulatory burden for health institutions meeting these conditions.

The HPRA is actively seeking to communicate on the upcoming changes which will impact health institutions. The changes do not apply until May 2022 but we are committed to raising awareness of these changes and providing support to health institutions preparing for the IVD Regulation. The HPRA is currently developing a survey for health institutions to assist understanding the current use of this exemption under the IVDD and to identify any concerns that health institutions may have. We encourage any health institution with questions on this topic to contact us devices@hpra.ie.

HPRA Process for Certificates of Free Sale

In line with continued improvements to the submission process for applications for certificates of free sale, it has been decided that it will no longer be necessary to provide a notarised document when applying for certificates of free sale for medical devices.

This means that, while all other requirements for the provision of correct documentation will remain, the requirement for a notary public stamp on either a declaration of conformity or manufacturer's statement will not now be required.

The HPRA [Guide to Applications for Certificates of Free Sale for Medical Devices](#), which is available from the HPRA website, outlines the information and documentation required when making an application for certificates of free sale.

Queries should be sent to exports@hpra.ie.

Commission Proposal to Delay the Implementation of the Medical Device Regulation (MDR)

The Medical Device Regulation (MDR) entered into force in May 2017 and was due to become fully applicable on 26 of May 2020 after a three-year transition period. However, the global outbreak of COVID-19 has placed unprecedented and unexpected pressures on economic operators, notified bodies, and competent authorities.

With the above in mind and the acknowledgement that patient health and safety are central to the work of the MedTech sector, the European Commission announced on 25 March 2020 that work on a proposal to postpone the application date of the MDR for one year is ongoing. The Commission aims to submit this proposal in early April to the

Parliament and Council for adoption before the end of May. The proposal is specific to MDR, and does not extend to the *In-Vitro* Diagnostic Regulations (IVDR) which becomes fully applicable from May 2022 after a five-year transition period.

The Commission's proposal will allow competent authorities, notified bodies, manufacturers and other stakeholders to focus fully on urgent priorities related to the COVID-19 outbreak. However, if the proposal is adopted by the Council and Parliament economic operators should endeavour to become fully MDR compliant during this additional 12-month transition period. Any updates on the proposal will be published on the HPRA's website.

This extension to the current implementation period will maintain the status quo for an additional 12 months and will provide all stakeholders with additional time to become MDR compliant.

The HPRA will continue to support our stakeholders with the implementation of the MDR and acknowledges the significant effort made by economic operators to be MDR compliant by 26 May 2020.

DG Santé in the Commission has issued a [statement](#) on the proposal, and further information on the Commission's announcement can be found [here](#).

Notified Bodies – “State of Play”



Notified bodies play an integral role in ensuring medical devices are safe and perform effectively for patients and users throughout Europe. These bodies are responsible for assessing the conformity of medical devices of certain risk classes based on legislative requirements. When requirements are met, notified bodies issue CE certification, which allows for the placing of medical devices on the European market for set periods. Notified bodies continue to monitor the performance of manufacturers and their medical devices over the course of the certification period and are required to suspend or withdraw certification where manufacturers no longer meet legislative requirements.

European national authorities appointed under national law are responsible for the designation, notification and oversight of notified bodies in their territory. Strengthening of legislation and associated requirements for the oversight of notified bodies has been a recurring theme in recent years, particularly with the onset of mandatory joint assessments of notified bodies. Joint assessment teams comprised of inspectors from the European Commission and national experts from Member States perform European joint assessments in conjunction with the local national authority. This collaborative approach aims to ensure notified bodies are assessed in a

consistent and harmonised manner and meet all relevant requirements of the legislation. Requirements for notified bodies and authorities responsible for notified bodies have been further defined and expanded upon in the new Medical Devices and *in vitro* Diagnostic Medical Devices Regulations.

Existing and prospective notified bodies looking to operate under the Regulations have been able to submit applications for designation to national authorities since November 2017. Applicant bodies are required to provide documentation demonstrating how they will meet the requirements of the Regulations and are required to undergo a European joint assessment as part of the application process.

At the onset of this new process, the initial rate of applications received by national authorities from existing and prospective notified bodies was lower than anticipated. Variance in the quality of applications resulted in delays in the scheduling of on-site assessments and in the subsequent development of CAPA plans. This, together with a number of diverging opinions between joint assessment teams and national authorities in the early days of the process, led to a lower rate of designations and notification of notified bodies under the Regulations than anticipated.

Today, most diverging opinions have been resolved and fewer delays are evident in the processing of applications. In 2019, the Commission along with the Medical Devices Coordination Group (MDCG) agreed to use a written procedure to expedite MDCG recommendations for designation, allowing recommendations to be issued outside of scheduled MDCG meetings. Given the reduction in diverging opinions and the onset of the written procedure, a steady increase in the number of notified bodies being designated and notified under the Regulations has been noted and it is hoped that more notified bodies will be operating under the Regulations in the coming months.

Recent data available indicates that 55 applications were received by European national authorities with 44 of these under the Medical Devices Regulation and 11 of these under the *in vitro* Diagnostic Medical Devices Regulation. This is an indicator that approximately 86% of notified bodies designated under the Medical Devices Directives and approximately 50% designated under the *in vitro* diagnostic Medical Devices Directives have applied to continue their activities under the Regulations. The majority of applicants have now undergone the on-site assessment phase of the process. Further progress is being made in the development and finalising of CAPA plans by applicants. Once applicants implement CAPA plans, national authorities can complete their final assessment reports and present the applicant for designation to the MDCG.

Currently, there are 12 notified bodies operating under the Medical Devices Regulation and three notified bodies operating under the *in vitro* diagnostic Medical Devices Regulation. There are other applicants at the final stages of the designation process and therefore more notifications will be pending in the short term.

The HPRA is the national authority appointed by the Department of Health with responsibility for the designation, notification and oversight of notified bodies in Ireland. The National Standards Authority of Ireland (NSAI) operates as a notified body in Ireland and has recently completed the designation process to become a notified body under the Medical Devices Regulations.

The HPRA has recently formed a dedicated notified body team in support of the European notified body system to perform designation and oversight activities in Ireland but also to support the European joint assessment programme. The HPRA is an active member of the Notified Body Operation (NBO) working group, which is one of a number of MDCG interest groups currently developing guidance and information in support of the notified body system. Documents developed through the NBO working group that have been endorsed by the MDCG are available on the [Commission website](#).

Prospective applicants looking to become notified bodies in Ireland should contact devices@hpra.ie to discuss the application process and the requirements of the new Regulations. Further details are available on our notified body page on our website.

MDCG Endorsed Guidance Documents

The Medical Devices Coordination Group (MDCG) met on 11 March and endorsed a number of guidance documents developed by the Working Groups in accordance with their work plans. Guidance documents endorsed by the MDCG will continue to be published on the EU Commission [website](#). The most recent documents endorsed include:

[MDCG \(2020-2\)-Guidance on Class I transitional provisions under Article 120 \(3 and 4\) – MDR](#)

In this guidance document, MDCG outlines the conditions manufacturers of Class I devices need to meet to benefit from the expansion of the transition period (Article 120 (3)) to cover their products. In summary, for manufacturers to make use of this transitional period outlined in article 120 (3) and (4) of the MDR, the Declaration of Conformity must be drawn up before the date of full application of the MDR.

[MDCG \(2020-3\) Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD](#)

The intended purpose of this guidance is to provide clarity on any changes to a medical device which may be considered as a 'significant change in design or a change in the intended purpose' as per Article 120 (3) of the MDR. The paper presents, in an Annex, several flowcharts which provide a roadmap to assist manufacturers and notified bodies in deciding whether or not a change is considered significant in the design or intended purpose of the device.

[MDCG \(V2\) Implant Card relating to the application of Article 18 Regulation of the MDR](#)

The purpose of this MDCG guidance document is to outline the intended use, content and information to be provided by the manufacturer on the Implant Card (IC) and a definition of the fields to be completed by health institutions and healthcare professionals. Additionally, the document recommends the use of national symbols on the IC to avoid the need for nation-specific versions. However, the guidance lacks a symbol for 'device type', leading the MDCG to recommend including the information in different languages. Example mock ups of ICs and informative leaflets explaining how to complete the IC are also included as part of the guidance.

[\(MDCG 2020-1\) Guidance on Clinical Evaluation \(MDR\) / Performance Evaluation \(IVDR\) of Medical Device Software](#)

This document seeks to cover the appropriate level of clinical evidence for medical device software to meet the requirements of the MDR and the IVDR. The guidance states that software is subject to the same clinical and performance evaluation principles as physical devices and IVDs, but also provides specific details applicable to software, and provides high-level examples of different clinical evaluation strategies for different types of products.

[\(MDCG 2019-15\) Guidance for Class I manufacturers](#)

In December, the Commission published a guidance document for Class I manufacturers which provides further detail on the obligations and responsibilities of Class I manufacturers. Key obligations include having a quality management system in place and appointing a person responsible for regulatory compliance.

In addition to this guidance document, the HPRA would also like to highlight the two corrigenda that were adopted by the European Parliament and Council to date. While the first corrigendum was introduced to correct editorial mistakes and typos, a second corrigendum was adopted in December 2019 and is significant for Class I manufacturers. Under the second corrigendum, all class I medical devices 'up classified' under the MDR will be able to avail of the Article 120 transition provisions. While this derogation allows devices with an MDD certificate to continue to be placed on the market up to 2024, there are a number of restrictions associated with its application. This extended scope of the transition provisions excludes devices which remain class I under the MDR.

Register of Economic Operators and Devices under the EU Device Regulations (EUDR)



In the drafting of the EU Device Regulations (EUDR) it was envisaged that there would be a centralised European database on medical devices (EUDAMED). A database where Economic Operators could register themselves and where applicable their associated devices and IVDs. However, in October 2019, the EU Commission announced that it will only be possible to make EUDAMED operational once the entire system and its associated modules have achieved full functionality and have been subject to an independent audit. As such, the EU Commission announced a delay to full functionality of EUDAMED until 2022 at the earliest.

The EU Commission has continued to work intensely on the development of Eudamed and it is now proposed that each module of the system, as soon as it is ready, will be made available on a voluntary basis. Regarding the Economic Operator registration module, it is anticipated that a voluntary registration may be the first module that is made available. Updates on the progress of this work will be made available on the Commission's [website](#).

Until the voluntary Economic Operator registration module is available on Eudamed, the HPRA is asking that Economic Operators established in Ireland, wishing to register under the EUDR, register their organisation and their associated devices with the HPRA. To facilitate this, the HPRA has established an interim EUDR registration process. The process involves initially registering an organisation and then registering devices/IVDs linked to that organisation number. The detailed steps can be found on the HPRA [website](#).

As outlined above the Commission is working on a proposal to postpone the application date of the Medical Devices Regulation (MDR) for 12 months. If this proposal is adopted by the European Parliament and European Council, the HPRA will continue to accept registrations under the Medical Device Directives and the MDR for the additional 12-month transition time.