Bird & Bird & COVID-19 Medical Devices Q&A

Emergency legislation / Regulatory relaxation during COVID-19 pandemic

Contents

Introduction

Background

Due to the COVID-19 pandemic, many countries have enacted emergency legislation removing certain regulatory barriers and exempting products from regulatory approval requirements. This allows unregistered products to be used or already registered products to be used for non-indicated conditions. The emergency legislation will define the products that are exempted and also from which provisions they have been exempted. There may also be an expiry date stated for the emergency legislation.

Europe

The European Commission has taken several measures in order to address the issues created by the Coronavirus crisis in the manufacture and supply chain of medical devices and In-vitro diagnostics.

As far as Medical devices are concerned, Member States can authorise derogations from conformity assessment procedures for medical devices, according to Article 11(13) of Directive 93/42 (MDD) and Article 59 of Regulation 2017/745 ("MDR").

In this regard, the EC published a Q&A on Conformity assessment procedures for protective equipment as well as a Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. According to the Recommendation, national competent authorities may authorise products that ensure an adequate level of health and safety in accordance with the essential requirements on the EU market, even though the conformity assessment procedures, including the affixing of CE marking, have not been fully finalised.

In exceptional circumstances, products can be placed on the market even if the certification procedures have not been initiated and no CE marking has been affixed upon them, if the following cumulative conditions are fulfilled:

a the products are manufactured in accordance with one of the EN standards or in accordance with any of the other standards referred to in the WHO guidelines or a technical solution ensuring an adequate level of safety;

b the products are part of a purchase organised by the relevant Member State authorities;

c the products are only made available for the healthcare workers;

d the products are only made available for the duration of the current health crisis; and

e the products are not entering the regular distribution channels and made available to other users.

A draft proposal amending the MDR (and deferring the application of certain provisions) allows the European Commission to extend, in exceptional cases, the validity of a national derogations (under art. 11 MDD) for a limited period of time to the territory of the Union ('Union-wide derogation'). The Commission would thus be able to adopt Union-wide derogations in response to national derogations in order to address potential shortages Union wide of vitally important medical devices in an effective manner. This provision would be of immediate effect.

For IVD's, Art. 9(1) and 9(2) of Directive 98/79 ("IVDD") (and Article 54 of Regulation - "IVDR") provides equally for derogations from CE marking and conformity assessment procedures.

There is currently no pending draft proposal to defer the entry into force of some provisions of the IVDR including the powers for "Union-wide derogations".

The European Commission published however an Implementing Decision 2020/439 of 24 March 2020 on the harmonised standards for in vitro diagnostic medical devices drafted in support of the MDDD. These harmonised standards for in vitro diagnostic medical devices may not be used to confer presumption of conformity with the requirements of Regulation 2017/746.

Asia-Pacific ("APAC")

There is no single harmonised approach for medical device regulation in countries within the APAC region and each country has its own medical device registration system.

This means that during the COVID-19 pandemic, some countries in the APAC region have implemented emergency legislation to expedite the approval procedure for medical equipment used for the diagnosis or prevention of COVID-19, whilst others have not.

China, for example, has enacted extensive emergency legislation for expedited approval of manufacturing sites and medical devices for COVID-19. Provincial level legislation has also been enacted to enable the expedited approval of manufacturing sites and medical device products.

Hong Kong, with its current voluntary device registration process, has not enacted any specific COVID-19 related requirements, preferring to rely on its current system. Other countries, such as Australia and Singapore, have enacted emergency legislation that contains specific requirements for manufactures and importers to meet for the designated types of medical devices subject to the altered regulatory provisions.

Overall, there is a requirement to continually monitor this changing environment. The various provisions enacted are all valid for different periods and there is no coordinated approach to the issue across the APAC region.

This document does not constitute legal advice, if you require more information please feel free to reach out to the country contacts in this document.

Australia

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes for certain medical devices (MDs) and in-vitro diagnostics (IVDs) for COVID-19. • MD (Protective Equipment): Therapeutic Goods (Medical Devices—Face Masks and Other Articles) (COVID-19 Emergency) Exemption 2020 • MD (Ventilators): Therapeutic Goods (Medical Devices—Ventilators) (COVID-19 Emergency) Exemption 2020 • IVD: Therapeutic Goods (Medical Devices—Accredited Pathology Laboratories) (COVID-19 Emergency) Exemption 2020
2	**Do the emergency provisions have an expiry date?**	Yes. • MD (Protective Equipment): 31 January 2021 • MD (Ventilators): 31 January 2021 • IVD: 31 January 2021
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes. MD (Protective Equipment): Medical devices that are disposable face masks, disposable gloves, disposable gowns, and protective eye wear in the form of goggles, glasses or visors, which are designed to be worn by individuals to prevent the transmission of organisms. MD (Ventilators): Medical device that are ventilators manufactured in Australia in accordance with the minimum technical requirements specified in the document, Ventilator for COVID-19 use in Australia (version 1.0) published by the Therapeutic Goods Administration on 7 April 2020.
4	**Do the emergency provisions stipulate which IVDs are included?**	Yes. IVD: Medical devices that are IVD medical devices used for the diagnosis, confirmatory testing, prevention, monitoring, treatment or alleviation of COVID-19.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes. The Therapeutic Goods Administration.
6	**What are the products exempted from?**	**MD (Protective Equipment): Relevant kinds of medical devices are exempt from:** • Division 1 of Part 4-2 of the Therapeutic Goods Act 1989 (Cth) (Act) (essential principals); and • Division 1 of Part 4-3 of the Act (conformity assessment procedures); and • Part 4-4 of the Act (conformity assessment certificates); and • Part 4-5 of the Act (including medical devices in the Register). when imported, exported, manufactured or supplied to deal with the

		threat to public health caused by COVID-19. **MD (Ventilators): Relevant kinds of medical devices are exempt from:** • Division 1 of Part 4-2 of the Act (essential principals); and • Division 1 of Part 4-3 of the Act (conformity assessment procedures); and • Part 4-4 of the Act (conformity assessment certificates); and • Part 4-5 of the Act (including medical devices in the Register). in order to deal with the threat to public health caused by COVID-19. **IVD: Relevant kinds of medical devices are exempt from:** • Division 1 of Part 4-2 of the Act (essential principals); and • Division 1 of Part 4-3 of the Act (conformity assessment procedures); and • Part 4-4 of the Act (conformity assessment certificates); and • Part 4-5 of the Act (including medical devices in the Register). when imported, exported, manufactured or supplied to deal with the threat to public health caused by COVID-19.
7	**Are exempted products required to meet GMP?**	MD (Protective Equipment): there is no requirement to provide evidence that the product meets GMP. MD (Ventilators): there is no requirement to provide evidence that the product meets GMP – although, note the technical requirements referred to above. IVD: there is no requirement to provide evidence that the product meets GMP.
8	**Are there specific procedures to be followed?**	No, standard application requirements if you wish the products to be formally registered (NB – surgical masks are Class I in Australia and are self-certified).
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	MD (Protective Equipment): No. MD (Ventilators): Yes. IVD: No. MD (Ventilators): Prior to supply of the specified kind of medical device to the hospital, the relevant manufacturer must: i. provide to the Therapeutic Goods Administration a set of documents comprising copies of the test procedure, test results and risk analysis undertaken by the relevant manufacturer in relation to the ventilator, and a declaration that the ventilator has been manufactured in accordance with the minimum technical requirements; and ii. obtain written permission from the Therapeutic Goods Administration that, following consideration of the set of documents mentioned in subparagraph (i), the supply of the ventilator to the hospital may proceed.
10	**Are there any additional requirements that must be met for a product to be supplied?**	MD (Face-Masks): medical devices must only be imported, exported, manufactured or supplied by a person under a contract between the person and the Australian Government Department of Health, or agency acting on their behalf. The exemption does not permit the general supply of these items by sponsors to health care facilities or consumers.

		MD (Ventilators): the ventilator must be manufactured for supply to a hospital in an Australian State or Territory. IVD: The IVD devices must only be imported, exported, manufactured or supplied by a laboratory that is a state or territory member of the Public Health Laboratory Network. NB – all medical devices sold in Australia require an Australian sponsor registered with the TGA.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes - to some degree. MD (Protective Equipment): Records must be kept by the supplier in relation to the importation, exportation, manufacture and supply - and they must be available for the government to review on request. MD (Ventilators): the manufacturer must keep records in relation to the manufacture and supply of the ventilator and on request from the Therapeutic Goods Administration, the relevant manufacturer must make the records available to the Therapeutic Goods Administration. MD (Ventilators): within the relevant period of time the relevant manufacturer must provide to the Therapeutic Goods Administration information relating to: i. any malfunction or deterioration in the characteristics or performance of the ventilator that might lead to a serious threat to public health, or to the death of a patient or user of the ventilator, or to a serious deterioration in his or her state of health; or ii. any technical or medical reason for the malfunction or deterioration mentioned in subparagraph (i) that has led the relevant manufacturer to take steps to recall the ventilator. The relevant period of time for providing the information mentioned above is: i. in relation to information that represents a serious threat to public health—48 hours after the relevant manufacturer becomes aware of the information; or ii. in relation to all other information—10 days after the relevant manufacturer becomes aware of the information. IVD: the laboratory or the person importing must keep records in relation to such importation, manufacture and supply of the relevant kinds of medical devices - and they must be available for the government to review on request.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	Yes. Customs in Australia will review incoming shipments of medical products for commercial use and determine if they are on the Australian Register of Therapeutic Goods or subject to an exemption. Selling medical devices in Australia without appropriate approval can be either a criminal or civil offence.
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No.

14	**Is there any other relevant information related to medical devices and IVDs during this period?**	Yes, the TGA is expediting the review of products submitted to them for COVID. Once approved, these products will be legally registered in Australia. Other updates are regularly provided through the TGA website.

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Belgium

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes. For MD and IVD, a general guidance ("*Circulaire*") has been issued by the Minister of Health in order to ease the manufacturing of medical devices for health care institutions. This Guidance provides exceptional rules applicable to the manufacturing of MD for health care institutions and the re-use of the reprocessing of medical devices for single use. In addition to this, an additional guidance has been published regarding the conformity assessment of chirurgical masks. The Federal Authority for Medicines and Health Products (FAMHP) has indeed noted that several surgical masks do not have the necessary declarations, certificates and test reports to demonstrate unequivocally that they meet the requirements of the applicable European standard (EN 14683:2019 + AC: 2019) or one of the international standards that are currently also accepted on an exceptional basis (ASTM F2100, YY 0469:2011 and YY/T 0969-2013). Due to the high level of needs in this crisis situation and in order to reduce the significant shortages of masks, the FAMHP provided guidelines for verifying the compliance and suitability of surgical mouth masks and developed an alternative and simplified test protocol (Alternative Test Protocol (ATP) As far as other categories of masks are concerned (namely masks for personal protection purposes), the Federal Ministry of Economy has implemented the European Recommendation n°2020/403 of the European Commission relating to the assessment procedure of conformity of personal protective equipment. These masks are not MD or IVDs but are subject to the Regulation n°2016/425 of 9 March 2016 on personal protective equipment. According to the guidance of the Ministry of Economy, the marketing of personal protection masks without bearing a proper CE marking delivered by a notified body is allowed provided that these masks are only be made available to healthcare workers during the current crisis and do not enter regular distribution channels. Additional information is accessible on the following link. The present document has been drafted in light of the general guidance, *"Circulaire"*.
2	**Do the emergency provisions have an expiry date?**	Yes. No specific expiry date has been specified. However, the measures are only applicable during the COVID-19 crisis. The expiry date is expected to be defined by the Federal Authority for Medicines and Health Products.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes. The medical devices covered by the guidance are those regulated by the MDD, MDR, IVDD and IVDR. The Guidance also covers the

		accessories of these devices.
4	**Do the emergency provisions stipulate which IVDs are included?**	No.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes. The Federal Authority for Medicines and Health Products
6	**What are the products exempted from?**	MD: the medical devices are exempted from the current regulatory requirements (including the CE marking). This exemption is however not applicable to MD emitting ionising radiations. IVD: the in vitro medical devices are exempted from the current regulatory requirements (including the CE marking). However, this exemption is not applicable to IVD emitting ionising radiations.
7	**Are exempted products required to meet GMP?**	MD: The guidance does not refer to GMP. That said, in the notification of the products to the abovementioned competent authority, the manufacturer of the products should identify the ISO norms or equivalent norms used in the following areas: (i) quality system; (ii) risk assessment system; (ii) systems in place for the biocompatibility of the materials. IVD: The abovementioned rules are also applicable to IVDs. The Guidance does not provide specificities for IVDs.
8	**Are there specific procedures to be followed?**	Yes, a notification process has been put in place by the guidance. The appropriate documents to be notified to the Federal Authority for the Medicines and Health Products are accessible through the following link
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes. In addition to personal data relating to the concerned hospital and the external subcontractor, the notification document must contain following information: (i) the description of device; (ii) the methodology applied for the device; (iii) the target population; (iv) the quality management system and risk management system; (v) the biocompatibility testing.
10	**Are there any additional requirements that must be met for a product to be supplied?**	As far as the manufacturing of medical products are concerned, the guidance provides a specific derogation for "in house" medical products, i.e. medical products manufactured within health care institution for their own use. The guidance provides that a MD manufactured by a third-party for an institution may be considered as an "in house" MD under specific conditions: • The device should be manufactured during the COVID19 situation from 13 March 2020 to the end date which will be defined by the FAMHP; • The original product is no longer available in the institution within a reasonable timeframe for the treatment of the patient; • The sub-contractor fills in the notification document to the competent authority in which it identifies the ISO norm or equivalent norm applied in the manufacturing of the MD; • The sub-contractor ensures the traceability of the MD by documenting the list of health care institution it provides; • The health care facility or its subcontractor must proceed to a

		specific notification to the Agency for Medicines and Health Products.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes – to some degree since records must be kept by the supplier or the health care facility. In addition, health care facilities must keep a traceability of sample of patients examined with an in vitro MD.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	Nothing is specifically provided in this regard in the guidance.
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	If yes, what are the provisions? Nothing is specifically provided in this regard in the guidance.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	The guidance also provides specific rules to be followed in order to re-use of medical devices initially intended for a single-use.

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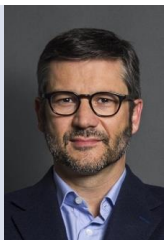

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China & Hong Kong

China		
1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes, for both medical devices (MD) and in-vitro diagnostics (IVDs). Emergency Approval Procedures for Medical Devices issued by NMPA (National Medical Products Administration) in 2009, which apply to both medical devices (MD) and in-vitro diagnostics (IVDs) for public health emergencies.
2	**Do the emergency provisions have an expiry date?**	No. According to the Emergency Approval Procedures for Medical Devices, which are still active now, NMPA can decide the time to initiate and terminate such emergency approval procedures in light of the situation and development of the public health emergency. NMPA has initiated the emergency approval procedure due to the COVID-19 outbreak in January 2020, but to date, there is no information from NMPA on the expiration date.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes Emergency Approval Procedures for Medical Devices apply to medical devices used for the public health emergency when there is no product of the same kind marketed in China, or the supply of products cannot meet the emergency needs (requires confirmation by NMPA).
4	**Do the emergency provisions stipulate which IVDs are included?**	Yes, Emergency Approval Procedures for Medical Devices also apply to IVDs, therefore the same provisions as Q3 will apply.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	No. The Emergency Approval Procedures for Medical Devices provide the accelerated approval of registration for medical devices. It does not provide provisions for the use of unregistered products. Devices are still required to be registered in China (i.e. Class II and Class III medical devices). Class I medical devices must be notified on a recordal basis.
6	**What are the products exempted from?**	The medical device products are not exempted from registration/recordal requirements.
7	**Are exempted products required to meet GMP?**	N/A as no medical device products are exempted from the regulatory requirements.

8	**Are there specific procedures to be followed?**	Yes, the Emergency Approval Procedures for Medical Devices include (1) a procedure to determine whether a medical device is a product requiring urgent approval; (2) the expedited approval procedures that must be followed for such a medical device. 1 Procedure to determine Urgent Approval a The medical device manufacturer should inform the relevant provincial medical product administration ("MPA") of the emergent needs and the R&D status of the product. The MPA will then determine the R&D and manufacturing status of the medical device and, if necessary, conduct the technical evaluation of the product at an early stage. b The medical device manufacturer must provide to the NMPA the evidence to support that the medical device is subject to urgent approval. c NMPA will establish a specialist group to evaluate and examine the medical device and make the decision in 3 days on whether to apply the emergency approval procedure. d Once approved for the emergency approval procedure, the manufacturer/entity should submit the application for registration to the relevant MPA and the review will then proceed in accordance with the procedure. 2 Expedited approval procedure a Once the application materials have been filed with the MPA and receipt is acknowledged, it will mark the application as "emergency approval". b The MPA is required to complete the technical review for Class II medical device in 5 days and Class III medical device in 10 days after acceptance. The administrative process for approval will then be completed in 3 days. c The medical device testing institution will conduct the registration testing in 24 hours upon the receipt of the sample and issue the testing report as soon as possible. d The MPA will arrange the on-site assessment in 2 days upon acceptance of the application and issue the quality management system assessment report in time. e The overall time for approval will depend on the testing and the MPA responsible for the review.
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes According to the Emergency Approval Procedures for Medical Devices, the applicant needs to provide the emergent needs and R&D status of the product to the relevant MPA. They must provide to the NMPA the evidence to support that the medical device is subject to urgent approval before the product is accepted. Once approved for the emergency approval procedure, the manufacturer/entity should submit the application for registration to the relevant MPA.

10	**Are there any additional requirements that must be met for a product to be supplied?**	Yes Class I medical device manufacturer in China has to record its product with city level MPA. Class II and III medical device in China manufacturers require a manufacturing licence from the provincial-level MPA, who is required, under the Emergency Approval Procedures for Medical Devices, to determine within 5 days whether to grant approval. In addition, the business operation of Class II medical device manufacturers must also be recorded with the city-level MPA and the business operation of Class III medical device requires a licence from the city-level MPA.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes The Emergency Approval Procedures for Medical Devices does not address this issue. However, the post market obligations for the emergency medical devices should be subject to the post market obligations set out in the PRC Medical Device Regulation, including but not limited to (1) Regulations on Supervision and Administration of Medical Devices, (2) Measures for the Supervision and Administration of Medical Device Production, (3) Measures on the Supervision and Administration of the Business Operations of Medical Devices, (4) Administrative Measures for Medical Device-Related Adverse Event Monitoring and Re-evaluation and (5) Administrative Measures for Medical Device Recalls.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	N/A
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	Yes The Emergency Approval Procedures for Medical Devices provide that, after the initiation of the procedure, the review required will be conducted by different levels of MPA, and the relevant technical institutions, in line with set procedures. The local MPAs may also create the local policies for the emergency approval of COVID-19 medical devices. According to the 2020 No.11 Notice of Ministry of Finance and National Development and Reform Commission , the COVID-19 medical devices subject to emergency approval procedures are exempt from the registration fees from 1 January 2020 until further notice. On 7 February 2020, NMPA issued the Notice on Accelerating the Approval of Medical Protective Clothing Registration and Production License, which set out some provisional measures for the registration and production of medical protective clothing during the COVID-19 period, including the approval pursuant to the Emergency Approval Procedures for Medical Devices. On 15 February 2020, State Administration for Market Regulation ("SAMR"), NMPA and Chinese National Intellectual Property Administration ("CNIPA") co-issued the Ten Items to Support Resumption of Work and Production, which includes that the emergency

approval shall be carried out for entities that convert to produce relevant medical devices. It also simplified the production qualification approval procedure, combined product registration and production license inspection procedure, initiating the emergency testing procedure and recognizing part of the self-inspection report for the entities which convert to produce mask and protective clothing, etc. emergency supplies.

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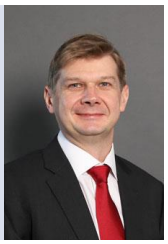

Czech Republic

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	No. The State Institute for Drug Control has only issued guidance regarding clinical trials of medical devices with respect to COVID-19 which is available here (in Czech language). There is however currently no guidance regarding emergency registration or supply of medical devices or IVDs.
2	**Do the emergency provisions have an expiry date?**	N/A
3	**Do the emergency provisions stipulate what type of medical devices are included?**	N/A
4	**Do the emergency provisions stipulate which IVDs are included?**	N/A
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	N/A
6	**What are the products exempted from?**	N/A
7	**Are exempted products required to meet GMP?**	N/A
8	**Are there specific procedures to be followed?**	N/A
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	N/A
10	**Are there any additional requirements that must be met for a product to be supplied?**	N/A
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	N/A
12	**Are there any additional issues to be addressed with importing unapproved (uncertified)**	No

	products e.g. customs waivers etc.?	
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	N/A
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	The State Institute for Drug Control has issued guidance regarding clinical trials of medical devices with respect to COVID-19 which is available here (in Czech language).

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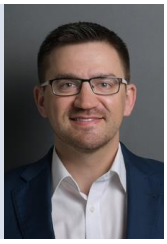

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Denmark

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	No guidance has yet been issued regarding emergency registration processes, but there has been issued legislation concerning the supply of certain medical devices. The emergency legislation passed is contained in Regulation on Special Measures Concerning the Supply of Medical Equipment and Personal Protective Gear (the "Regulation") issued under the Act on Measures Against Infectious Deceases as amended on 17 March 2020: https://www.retsinformation.dk/eli/lta/2020/253 The Regulation authorizes the Danish Medicines Agency to take special measures aiming at ensuring the supply of medical equipment and personal protective gear in connection with the handling of the COVID-19 decease. As part of such measures, the Danish Medicines Agency may order Danish manufacturers, importers, private hospitals, specialist doctors and dentists to report on their inventory of medical devices and to deliver such devices to the Danish regions and municipalities against payment. Furthermore, The Danish Medicines Agency may order that certain types of medical devices or protective gear may only be sold at pharmacies to specified groups of persons, and in limited amounts. Furthermore, The Danish Medicines Agency may set the price or a maximum price for a medical device or protective gear.
2	**Do the emergency provisions have an expiry date?**	Yes, 31 August 2020.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	No.
4	**Do the emergency provisions stipulate which IVDs are included?**	No.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	N/A
6	**What are the products exempted from?**	N/A
7	**Are exempted products required to meet GMP?**	N/A

8	**Are there specific procedures to be followed?**	N/A
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	N/A
10	**Are there any additional requirements that must be met for a product to be supplied?**	N/A
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	N/A
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	N/A
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	N/A
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No

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Finland

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes for certain medical devices (and also for certain PPE). • Finnish Medicines Agency Fimea's policy "Requirements for mouth/nose masks and gloves in COVID-19 situation" of 1 April 2020, here in Finnish. • Policy of the Ministry of Social Affairs and Health regarding sales of protective equipment for coronavirus of 17 April 2020, here in Finnish. With regard to IVDs, the Finnish Medicines Agency Fimea has published a letter for distributors and would-be distributors of Sars-CoV2 (COVID-19) tests in which Fimea reminds of the requirements for rapid COVID-19 tests (e.g. CE marking, declaration of conformity) and their appropriate marketing and asks for more information about the tests on the market. Fimea has not provided any exemptions or "emergency registration" for such rapid tests. According to Fimea, it is conducting targeted market surveillance of the compliance of COVID-19 tests and their appropriate marketing. It can also be noted that pursuant to Section 55 of the Finnish Medical Devices Act (629/2010), if a medical device or IVD does not yet have the CE marking, it is possible, under certain circumstances to apply for a temporary special permit from Fimea in order to place the product onto market.
2	**Do the emergency provisions have an expiry date?**	No. The policies regarding certain medical devices and PPE are in force only during the duration of coronavirus epidemic. Fimea shall update its policy when needed. The Ministry of Social Affairs and Health shall inform when its policy is no longer applicable.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes. Fimea's policy applies to the following medical devices used in protection against COVID 19 virus: mouth/nose masks (surgical masks) and gloves used in health care. The Ministry of Social Affairs and Health's policy applies to the following personal protection equipment (PPE) for professional use that can be used in protection against COVID 19 virus: filtering half masks (nonwoven masks), face and eye protectors, protective gloves, and protective clothes.
4	**Do the emergency provisions stipulate which IVDs are included?**	N/A
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes. With regard to the applicable medical devices, the assessment or special permit of Finnish Medicines Agency Fimea is required before placing onto market protectors with no CE marking. With regard to the applicable personal protective equipment (PPE), the Ministry of Social Affairs and Health is the market surveillance authority making prohibition decisions with regard to the PPE used in work. Also the divisions of occupational safety and health of Regional State Administrative Agencies are monitoring the PPE.

6	**What are the products exempted from?**	According to Fimea's policy pertaining to the applicable medical devices: • EU declaration of conformity is not required. However, the manufacturer of the protector must declare that the product itself fulfills the requirements to which it is subject. • CE marking is not required. • Registration is not required. However, the assessment or special permit of Fimea is required. According to the Ministry of Social Affairs and Health's policy pertaining to the applicable personal protective equipment (PPE): • EU type examination certification is not required, if the performance of the protector has been shown by an adequate test report. • EU declaration of conformity is not required. • CE marking is not required.
7	**Are exempted products required to meet GMP?**	No such guideline from the Finnish authorities is given.
8	**Are there specific procedures to be followed?**	With regard to the applicable medical devices, Fimea provides a form pertaining to placing mouth/nose protectors and gloves onto market (application for exemption/special permit).
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes. In the form referred to in Q8, the following information is requested from the applicant: • details of the applicant; • details of the medical device; • device specific requirements; • attachments (instructions, package labelling, test report, description and reasoning with regard to the correspondence to EN standard if needed, the declaration by the device manufacturer that the product fulfils the requirements to which it is subject).
10	**Are there any additional requirements that must be met for a product to be supplied?**	Fimea has provided that the products in question need to comply with certain EN standards or their equivalence with the said standards has to be shown. The products must have sufficient laboratory test reports. The Ministry of Social Affairs and Health has also provided requirements regarding applicable standards and testing for each applicable product type. The products need to have appropriate instructions and labelling.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	No exemptions have been provided in this regard. Thus, standard requirements should apply.
12	**Are there any additional issues to be addressed with importing**	The policies do not provide guidance on such issues.

	unapproved (uncertified) products e.g. customs waivers etc.?	
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No such immunity has been provided. It should be noted that Fimea has provided (with regard to special permit and medicinal products) that the releasing party is responsible e.g. for ensuring the appropriateness of the application when submitting the application to Fimea.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	Fimea has published a website Frequently asked questions (COVID-19)

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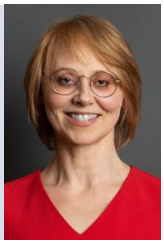

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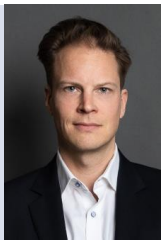

France

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes for medical devices (MD) (masks only) Interministerial instruction DGT/DGS/DGCCRF/DGDDI/2020/63 of 23 April 2020 relating to the implementation of the EC Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat
2	**Do the emergency provisions have an expiry date?**	Yes, 31 September 2020
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes, Surgical face masks corresponding to MDs (and personal protective equipment corresponding to FFP1, FFP2 and FFP3 masks that are not MDs)
4	**Do the emergency provisions stipulate which IVDs are included?**	N/A
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	The ANSM : the French Agency for medicines and health products which is the competent authority for medical devices
6	**What are the products exempted from?**	• Imported surgical face masks considered as medical devices can be made available on the French market without CE marking to **professionals** provided that a derogation under Article R.5211-19 of the French Public Health Code is obtained from the ANSM that should verify that the products present an adequate health and security level in compliance with the standards set out in appendix 2 to the interministerial instruction of 31 March 2020 • the surgical face masks imported by the State or requisitioned by the State can be made available without CE marking to health professionals provided that they comply with the standards set out in appendix 2 to the interministerial instruction of 31 March 2020 (no ANSM derogation is needed in such scenario)
7	**Are exempted products required to meet GMP?**	Not specified in the guidance
8	**Are there specific procedures to be followed?**	No other specific procedure than the ANSM derogation referred to under Q6 (ie derogation from the ANSM)
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	No other specific information that that referred to under Q6 (compliance with standards set out in appendix 2 to the interministerial instruction)
10	**Are there any additional requirements that must be met for a product to be supplied?**	See reply to Q6

11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Not specified in the guidance
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	N/A
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No

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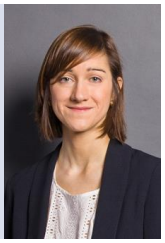

Germany

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes. The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM) published: • a guideline on face masks • on "emergency registration" • on Clinical Trials for Medical Devices
2	**Do the emergency provisions have an expiry date?**	No
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes. The emergency provisions explicitly refer to face masks and protective gear, but also include general information on the "emergency registration".
4	**Do the emergency provisions stipulate which IVDs are included?**	No
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes. Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM).
6	**What are the products exempted from?**	Under certain conditions, the products might be exempted from the requirement of a CE certificate.
7	**Are exempted products required to meet GMP?**	Yes
8	**Are there specific procedures to be followed?**	Yes. See link here.
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes. • Compliance with specific technical requirements: DIN EN 14683:2019-6 OR • Proper registration as medical device in Canada, Australia or the United States
10	**Are there any additional requirements that must be met for a product to be supplied?**	Yes • Application for emergency registration at medizinprodukte@bfarm.de
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event**	Yes. Depending on the contents of the "emergency registration".

	reporting and record keeping?	
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	No
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No

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Hungary

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	No, neither for medical devices (MD) nor in-vitro diagnostics (IVDs) for COVID-19.
2	**Do the emergency provisions have an expiry date?**	N/A
3	**Do the emergency provisions stipulate what type of medical devices are included?**	N/A
4	**Do the emergency provisions stipulate which IVDs are included?**	N/A
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	N/A
6	**What are the products exempted from?**	N/A
7	**Are exempted products required to meet GMP?**	N/A
8	**Are there specific procedures to be followed?**	No, standard application requirements are still in place if you wish the products to be registered.
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	N/A
10	**Are there any additional requirements that must be met for a product to be supplied?**	No, general rules apply.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	N/A
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	No, general rules apply.

13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No, general rules apply.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No, there is no legislation on MDs and IVDs during this COVID-19 pandemic period yet.

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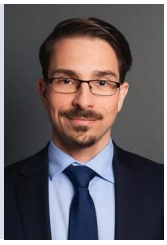

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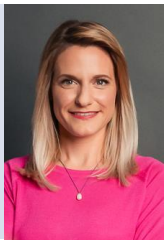

Italy

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes for MD. • MD: Face Masks and personal protective equipment (PPE) - link here.
2	**Do the emergency provisions have an expiry date?**	Yes • 31 July 2020
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes • Surgery mask for medical purpose and PPE (as protective eye wear in form of goggles, glasses or visors, disposable gloves, disposable gown, closed boots and shoes for work), which are designed to be worn by individuals to prevent the transmission of COVID-19.
4	**Do the emergency provisions stipulate which IVDs are included?**	No
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes The National Institute of Health ("Istituto Superiore di Sanità" or "ISS") regarding the face masks, the National Institute for Insurance against Accidents at Work ("INAIL") for PPE.
6	**What are the products exempted from?**	Those MD relevant to protect from COVID-19 transmission.
7	**Are exempted products required to meet GMP?**	No. Currently exceptional measures impose only to provide adequate documentation concerning the implementation of a Quality Management System, which does not need necessarily to be certified.
8	**Are there specific procedures to be followed?**	Yes. (i) the manufacturers, importers and those who place surgical masks or PPE on the market ("applicant") shall send (via PEC) a self-certification to the competent body (see Q5) in which, under their own exclusive responsibility, shall certify the technical characteristics of the surgical masks and/or PPE and shall declare that those products respect all the safety requirements of the current legislation; (ii) within 3 days following the submission of the application, the applicant shall transmit to the competent body any element useful for the validation of the surgical masks or PPE covered by the application itself, and if it is not possible, the applicant shall inform the competent body regarding how many days such additional elements will be transmitted; in the meantime, the applicant can start the manufacture; (iii) within 3 days after receipt of all documents, the competent body shall decide regarding the compliance of the surgical masks and/or PPE with the current regulations. See link here for further information.

9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes. See Q8.
10	**Are there any additional requirements that must be met for a product to be supplied?**	No
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes, the manufacturer shall implement a Quality management system able to control and manage, through defined procedures, the product placed on the market. In particular such procedures shall manage the traceability activities (both on the raw materials and products placed on the market).
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	Yes. Italian Customs, and other security force, will review incoming shipments of medical products for commercial use and determine if they are subject to an exemption. Selling uncertified or unapproved MD and/or PPE can be either a criminal and/or civil offence.
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No

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Netherlands

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes, for both medical devices (MD) and in-vitro diagnostics (IVDs) for COVID-19. MD/IVD: Government of the Netherlands: "*Frequently asked questions concerning protective equipment healthcare professionals*" (in Dutch: link), News Release 11 August of the Health and Youth Care Inspectorate: "*Medical devices only permitted with CE-marking as of 1 September*" (in Dutch: link).
2	**Do the emergency provisions have an expiry date?**	No, at the moment it applies as long as there are shortages of medical devices due to COVID-19. This may be subject to change.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes, it relates to surgical mouth caps, gloves and supplies for performing corona tests. The conditions published by the Health and Youth Care Inspectorate in March still apply to these types of medical devices (in Dutch: link). This means that where a substitute qualified medical device (containing the CE-mark) is not available, while the healthcare provider has specifically requested the medical device and will carry the responsibility for the use thereof. In addition, it is allowed to keep the stocks of medical devices without the CE – mark in case of shortages. Also, which of the emergency provisions are applicable, depends on the type of medical devices and their classifications, see the answer to question 8.
4	**Do the emergency provisions stipulate which IVDs are included?**	See answer to Q3.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes The Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd) oversees the use of unregistered medicinal devices that do not fall within the responsibility of the National Resources Consortium. The National Resources Consortium was created by the Ministry of Health for the current crisis to purchase in bulk, without profit motive, medical devices of which a shortage is impending. At the moment they are responsible for the following products, which list (in Dutch) may be updated: • FFP1, FFP2 en FFP3 masks • Surgical masks, type 2R • Protective coats • Protective eyewear • Aprons • Surgical Masks • Research gloves • Diagnostic tests (including PCR-material, swabs and media) • Disinfectants • Infusion pumps

		• Syringe pumps • Perfusors For the sake of completeness we mention that the Inspectorate for Social Security and Employment (Inspectie Sociale Zekerheid en Werkgelegenheid) oversees the use of personal protective equipment falling within EU Regulation 2016/425, such as face masks brought on the market as such equipment. The Inspectorate also temporarily allows personal protective equipment without a CE-marking meant to protect professional healthcare providers against COVID-19. The rules applied follow EC Recommendation 2020/403.
6	**What are the products exempted from?**	MD/IVD: the medical devices mentioned in Q3 do not require a CE marking and it is not required that they have gone through the normal assessment procedure. This exception only applies if 1) the health care provider explicitly requests the alternative medical devices, 2) holds responsibility and 3) if there are no approved alternatives available.
7	**Are exempted products required to meet GMP?**	MD/IVD: there is not an official GMP requirement for the unregistered products, however if the product is not manufactured according to GMP it will be assessed on a case by case basis if this is an issue, as with all requirements.
8	**Are there specific procedures to be followed?**	Yes This depends on the product type. • Class I products: no prior notification to the Health and Youth Care Inspectorate or other action required • Class IIa/b and III products: prior notification required to the Health and Youth Care Inspectorate via email to meldpunt@igj.nl with in the subject line "*Corona verzoek zorgaanbieder mhm klasse II/III*". Additional questions or information may be required. • Medical devices and IVDs (tests) that are bought through the National Resources Consortium: notification to take place also via the aforementioned mail address. It is then forwarded to the National Resources Consortium for further analysis. Additional questions or information may be required. • The aforementioned may be amended, current information can be found here in Dutch.
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes • Class IIa/b and III products – Manufacturer's name and address (including e-mail address) – Date of request from healthcare provider – Details of healthcare provider – Name and type of medical device for which, according to the healthcare provider, there is a shortage as a result of COVID – 19 (including the statement of the healthcare provider) – Name and type of medical device supplied as an alternative – Quantity of medical device supplied

		– Overview of relevant standards – If present: indication of other certificates present – If present: status of conformity procedure CE • Medical devices and IVDs (tests) that are bought through the National Resources Consortium Specifications and information concerning the technical and clinical requirements of the products. The products must meet the guidelines set out by the National Institute of Public Health and the Environment. These are updated continually (link).
10	**Are there any additional requirements that must be met for a product to be supplied?**	No
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes All considerations and decisions must be recorded by healthcare providers, suppliers and manufacturers.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	No
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	There is no specific legislative protection for products imported and supplied under the emergency provisions.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No

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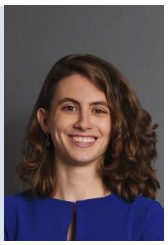

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Poland

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes, but only for certain medical devices (MD) such as medical face masks and/or disinfectants to be used as protective means against COVID-19. Resolution No. 33/2020 of the Council of Ministers of 20 March 2020 on specific solutions regarding the supply of personal protective equipment that is necessary to prevent the spread of the SARS-CoV-2 virus.
2	**Do the emergency provisions have an expiry date?**	Yes No longer than 30 days after the end of the epidemic status in Poland as announced by the Minister of Health in consultation with the Chief Sanitary Inspector.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	No, the emergency provisions state only that these are medical devices that help minimize the risk of the virus spreading. Information on the website of the Polish Ministry of Health were the emergency provisions are published indicates certain categories of medical devices in question, i.e. face masks, gloves, feet protectors, overalls, aprons and protective eye wear in the form of goggles, glasses or visors, which are designed to be worn by individuals to prevent the transmission of COVID-19.
4	**Do the emergency provisions stipulate which IVDs are included?**	N/A
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	No, but the general rules applying to supervision of medical devices in Poland should apply to such exempted products. The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL).
6	**What are the products exempted from?**	Relevant kinds of medical devices to be used as protective means against COVID-19 that are authorised for placing on the market in other countries than EU/EEA Member States.
7	**Are exempted products required to meet GMP?**	MD: as the stated products are exempted from the regulatory requirements, there is no requirement to provide evidence that the product meets GMP.
8	**Are there specific procedures to be followed?**	No, standard application requirements if you wish the products to be formally registered, including conformity testing and certification.
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	No
10	**Are there any additional requirements that must be met**	Exempted products can only be purchased by the Ministry of Health or other entities to which the Ministry delegated powers in this

	for a product to be supplied?	respect.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes. The emergency provisions do not provide for any exemptions in this regard. Thus, standard requirements apply.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	No
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No, there is no special "immunity" provided for in the emergency provisions.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	Applications for registration of medical devices clearly marked as related to COVID-19 by the applicant will be considered by URPL first (i.e. quicker).

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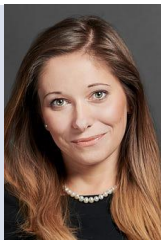

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Singapore

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes for hand sanitisers, masks, thermometers, protective gear, respiratory devices, and diagnostic test-kits for COVID-19. • Import of Hand Sanitisers, Masks, Thermometers and Protective Gear: Health Products (Import, Wholesale and Supply of Medical Devices — Exemption) Order 2020. See link here • HSA's Regulatory Position on Respiratory Devices: Supply for Management of COVID-19 Patients. See link here. • HSA Expedites Approval of COVID-19 Diagnostic Tests in Singapore via Provisional Authorisation. See link here.
2	**Do the emergency provisions have an expiry date?**	No, but the Health Sciences Authority of Singapore has indicated that the Provisional Authorisation for Diagnostic Tests is merely an interim measure in response to the current public health need for timely detection of COVID-19 infections.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes Hand sanitisers, masks, thermometers, protective gear for medical professionals and respiratory devices.
4	**Do the emergency provisions stipulate which IVDs are included?**	Yes Tests intended for the detection and/or diagnosis of COVID-19 infection.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes Health Sciences Authority of Singapore ("HSA").
6	**What are the products exempted from?**	Hand sanitisers: Approval need not be obtained for import Masks, thermometers and protective gear for medical professionals: License need not be obtained for import, but notification must be given of the intention to import for commercial use or beyond a certain quantity. Information on the brand and quantity of the devices must be provided to HSA, and importers must maintain proper sales and distribution records. Respiratory devices: HSA-registered anaesthesia machines with facilities capable of providing controlled ventilation or assisted ventilation as emergency ventilators for COVID-19 patients may be used as ventilators without approval from HSA. Upgrades or modifications to HSA-registered ventilators may be done prior to HSA approval, as long as these changes do not affect performance specifications and the requisite safety standards continue to be met. Information on modifications need only be submitted on a 6-month basis. Diagnostic test-kits: HSA has set up a provisional authorisation process intended for detection and/or diagnosis of COVID-19 infection, allowing test-kits which have received such authorisation to be supplied to healthcare institutions, private hospitals, medical clinics and clinical laboratories in Singapore.

7	**Are exempted products required to meet GMP?**	Most of the listed products are exempted from the regulatory requirements, and therefore there is no requirement to provide evidence that the product meets GMP. However, upgrades or modifications to HSA-registered ventilators must meet the requirements of the Health Products (Medical Devices) Regulations 2010. As the stated products are exempted from the regulatory requirements, there is no requirement to provide evidence that the product meets GMP.
8	**Are there specific procedures to be followed?**	Yes. Import of surgical masks and thermometers for personal use: Import of surgical masks, thermometers and/or protective gear for medical professionals for commercial or other purposes Notification to HSA for upgrades or modifications to respirators Provisional authorisation for diagnostic test kits: hsa_md_info@hsa.gov.sg
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes. For forms, please refer to the link above. For email to HSA seeking provisional authorisation, the following information must be included:- • A brief description of the test (test design, target biomarker, device technology, description of key functional elements, specifications, composition, accessories) • Intended purpose of the test • Information for Users (IFU) for the test • Summary of analytical validation (e.g. Limit of Detection, inclusivity, cross-reactivity, precision, interfering substances, Hook effect) and clinical data collected for the test where available • Summary of any planned or ongoing validation including clinical studies
10	**Are there any additional requirements that must be met for a product to be supplied?**	No
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes Importers of masks, thermometers and protective gear for medical professionals must **maintain proper distribution and sales records** according to the template form on the HSA website (https://www.hsa.gov.sg/announcements/regulatory-updates/import-of-hand-sanitisers-masks-thermometers-and-protective-gear). Where necessary, for example if certain brands of thermometers are recalled, **HSA may require these records to be submitted for review**. Local dealers of upgraded or modified ventilators are subject to **post-market duties and obligations** as stipulated in the Health

		Products Act and the Health Products (Medical Devices) Regulation 2010, including **reporting of adverse events arising from the use of these medical devices, reporting of Field Safety Corrective Actions and recalls related to these devices**. Where provisional authorisation of diagnostic test kits is sought, **periodic reports on specific data on the safety and/or performance of these tests will be required to be submitted to HSA post authorisation**, to assure the continued performance of these devices. If any safety or performance issues are observed, **HSA will require relevant follow up actions at the manufacturer's end**.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	No
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	No, there is no specific legislative protection for products imported and supplied under the emergency provisions.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	No

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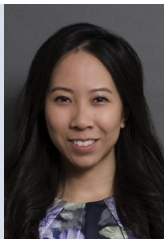

Slovakia

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes. As of 13 April 2020, the following "emergency" legislation shall apply in the Slovak Republic: The State Institute for Drug Control in the Slovak Republic (SIDC) *(in Slovak: "Štátny ústav na kontrolu liečiv")* issued a measurement on prioritised registration of human drugs to be applied for COVID-19 treatment. The Slovak parliament passed a laws authorising Ministry of Health of the Slovak Republic to adopt the resolution on (i) ban of export of human drugs available without medical indication or having no categorisation, as well as of medical devices, in-vitro diagnostics and dietetics goods categorised within the dietetics goods, (ii) limit and/or regulate the dispensation of human drugs available without medical indication or having no categorisation, as well as of medical devices, in-vitro diagnostics and dietetics goods categorised within the dietetics goods, (iii) regulate the prescription of human drugs available without medical indication or having no categorisation, as well as of medical devices, in-vitro diagnostics and dietetics goods categorised within the dietetics goods. Moreover, the mentioned laws limit the distribution (sale and transfer) of personal protective device, particularly filtrating facial half mask of risk category FFP2 and FFP3 to general public. The measurement of SIDC on prioritised registration of human drugs (registered and not registered within EU) to be applied for COVID-19 treatment (further as the MEASUREMENT only) - available in Slovak language here The laws passed by the Slovak parliament on adoption of some extraordinary measures in health care sector (further as the LAWS only) - available in Slovak language here Resolution of the Ministry of Health of the Slovak Republic on ban of export and supply of (i) registered human drugs available without medical indication and containing paracetamol, ibuprophenum, acethylsalicyl acid, (ii) unregistered drugs which therapeutic use is approved by Ministry of Health of the Slovak Republic and which contain antivirals for systematic use from ATC J05, hydroxychlorochinon and chlorochinon (passed by virtue of LAWS), and Measurement of the Ministry of Health of the Slovak Republic on ban on ordering and supplying the drug Plaquenil (reg. No.: 25/0505(70-C/S) under certain circumstances - both available in Slovak language here
2	**Do the emergency provisions have an expiry date?**	No and Yes. The MEASUREMENT does not refer to any particular expiry date.

		The LAWS refer to the period of the occurrence of extraordinary circumstances only (i.e. during the extraordinary situation – *in Slovak: "mimoriadna situácia"*, state of urgency – *in Slovak: "núdzový stav"* or state of emergency – *in Slovak: "mimoriadny stav"* declared by the relevant authorities in the Slovak Republic).
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes. Please see response in Q1
4	**Do the emergency provisions stipulate which IVDs are included?**	No, just general stipulation.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes. As per the MEASUREMENT, SIDC shall be authorised to approve registration of the human drugs to be applied for COVID-19 treatment in the Slovak Republic (either registered or not registered within EU). Please see thereto also last sentence in Q8 with respect to the temporary registration.
6	**What are the products exempted from?**	As per the MEASUREMENT, there are no particulars specified. It is stipulated only the registrations shall be handled with priority.
7	**Are exempted products required to meet GMP?**	As per the MEASUREMENT, there are no particulars specified. It is stipulated only the registration shall be handled with priority.
8	**Are there specific procedures to be followed?**	Yes. As per the MEASUREMENT, in case of registration of human drugs to be applied for COVID-19 treatment which have been already registered within EU, the MRP or RUP procedure may be followed. SIDC shall approve the registration within 7 days. This procedure shall precede the confirmation of SIDC on admission of prioritised registration. In case of registration of human drugs to be applied for COVID-19 treatment which have not been already registered within EU, the national registration procedure shall be followed. SIDC shall approve the registration within 30 days. This procedure shall precede the confirmation of SIDC on admission of prioritised registration. In addition, apart from the registration with SIDC it is possible to ask for a temporary registration of the human drug by the Ministry of Health of the Slovak Republic, in case this is reasonable for the protection of public health. More information can be found here.
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes. As per the MEASUREMENT, in case of registration of human drugs to be applied for COVID-19 treatment which have been already registered within EU, the following documentation shall be submitted to SIDC: (i) application for registration itself, (ii) relevant documentation from reference state, (iii) Commercial Register excerpt, (iv) confirmation on registration fee payment. In case of registration of human drugs to be applied for COVID-19 treatment which have not been already registered within EU, the following documentation shall be submitted to SIDC: (i) application for registration itself, (ii) Commercial Register excerpt, (iii)

		confirmation on registration fee payment, (iv) relevant documentation based on the particular application.
10	**Are there any additional requirements that must be met for a product to be supplied?**	As per the MEASUREMENT, there are no further particulars specified.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	As per the MEASUREMENT, there are no particulars specified.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	As per the MEASUREMENT and the LAWS, there are no particulars specified.
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	As per the MEASUREMENT and the LAWS, there are no particulars specified.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	All and any relevant information may be found in Slovak language at: https://www.health.gov.sk/Clanok?Hlavna-sprava-COVID-19 https://www.sukl.sk/ https://www.korona.gov.sk/

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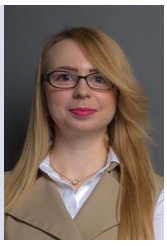

Spain

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes, but only for medical devices (MD). • Order SND/326/2020 of 6 April establishing special measures for the granting of exceptional licenses for the use of facilities and for the commissioning of certain medical devices without an EC mark in connection with the health crisis caused by COVID-19. The Spanish Agency for Medicinal Products and Medical Devices (AEMPS) has issued two Information Notes explaining the need for these exceptional measures and explaining how to handle the relevant applications. The links can be found here and here. • Resolution of 20 March 2020 of the Official Agency of Industry and Small and Medium-sized Companies on alternative specifications for PPE masks with EC marking.
2	**Do the emergency provisions have an expiry date?**	Yes • Order SND 326/2020: According to Article 6, the two exceptional measures established by the Order (exceptional and temporary license to manufacture some kind of medical devices and express authorization to commercialize some kind of medical devices without EC marking) may be granted only during the validity of the state of alarm. Besides that, the Information Note (which was mentioned in Q1) states that the validity of the (i) exceptional and temporary license to manufacture is 4 months; and (ii) the express authorization to trade in medical devices without EC marking is only valid during the state of alarm. • Resolution of 20 March 2020: In accordance with Article 3, the measures are applicable only for the duration of the exceptional situation for which they are intended (a time period not expressly defined in the resolution).
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes • Order SND/326/2020 refers exclusively to medical devices considered as disposable facemasks and disposable gowns. • With regard to artificial respirators, the AEMPS has expressly stated in an Information Note that they must continue to be governed by the general rules. Resolution of 20 March 2020 of the General Secretariat refers to facemasks as personal protective equipment (PPE).
4	**Do the emergency provisions stipulate which IVDs are included?**	No
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes Spanish Agency for Medicinal Products and Medical Devices (AEMPS).

6	**What are the products exempted from?**	• Order SND 326/2020: establishes two exceptional measures (these requests shall be processed as a matter of priority and urgency): – Firstly, it is allowed that the AEMPS may grant an exceptional license to manufacture disposable masks or disposable gowns or a temporary modification of the existing license. – Secondly, the AEMPS is allowed to grant express authorizations for the use of products without the EC marking. In these authorizations that enable the use of medical devices without EC marking, the AEMPS may also exempt from complying with the general health guarantees of Article 4 of Royal Decree 1591/2009, on medical devices (regarding the information provided). • Resolution of 20 March 2020: Allows three exceptional situations for acceptance of EPIS masks: – Purchase by the public authorities of PPE masks without EC conformity marking but which do comply with the equivalent markings according to NIOSH (USA) or KN95 (China) specifications. This purchase must be previously authorized by the Health Authorities and can only be supplied to health personnel. – Temporary exception to accept the commercialization of protective masks without EC marking that comply with the above specifications, after analysis by the Health Authority. – EC marking with another technical specification different from the harmonized standards. In any case, the labelling of these masks must comply with the provisions of article 4 of Order SND/354/2020, of 19 April, which establishes exceptional measures to guarantee access to the products recommended as hygienic measures for the prevention of COVID-19
7	**Are exempted products required to meet GMP?**	No, they are not exempted • Order SND 326/2020 establishes that: – Surgical facemasks: Must comply with UNE-EN 14683:2019+AC 2019 or ISO 22609:2004. – Disposable gowns: Must comply with UNE-EN 13795-1:2020 • Order SND/354/2020, of 19 April, establishes that disposable mask must comply with UNE 0064-1:2020, UNE 0064-2:2020 or UNE 0065:2020. Children's facemasks must also comply with UNE-EN 14682:2015.
8	**Are there specific procedures to be followed?**	Yes • Order SND 326/2020: Express authorization must be obtained
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes • Order SND 326/2020: The information note referred to in section Q1 states that reduced documentation must be submitted in respect of general formalities. This simplified information is: – **Exceptional and temporary license for manufacturing:** Company's deed; copy or request of the express authorization to use the medical device without EC marking; designation of the person who will manufacture the medical device and who will also have to carry out the final controls, indicating his training, experience and providing a contract and his ID card; description of the medical device to be manufactured, indicating the available means and describing the manufacturing process; description of

		the manufacturing facilities; description of the environmental and ventilation conditions of each working area; description of the daily cleaning procedures; description of the hygiene measures; description of the work flows (purchase of material, manufacture, control, dispatch to user); indication of subcontractors, if any. – **Express authorization for the use of masks without EC marking**: Information on the technical requirements of the products, copy of the labelling that must contain certain minimum information and certification of the UNE standards for each type of medical device.
10	**Are there any additional requirements that must be met for a product to be supplied?**	No, neither the Order nor the Resolution does not establish any exceptional rule in this respect.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	The Order and the Resolution does not establish any exceptional rule in this respect. Therefore, the general rules for reporting adverse incidents of medical devices to the AEMPS are applicable.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	Yes. The Royal Decree 8/2020, of 17 March, has streamlined the import of products allowing the use of IT solutions.
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	Yes • Order SND 326/2020: Article 5 states that the Spanish Authorities will only assume any possible liability that may be attributed to the granting of the exceptional license or to authorize the use of medical devices without the EC mark or with exceptional health guarantees if these two conditions are met: (i) that the medical device has been delivered to the Ministry of Health to treat those affected by COVID-19 and (ii) that no business benefit has been obtained.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	Yes, • On the 2nd March the AEMPS published an agreement to initiate a procedure to ban the export of masks and to request the prioritization of health centers and services in the distribution. • Article 4 of Royal Decree-Law 6/2020, of 10 March, allows the Health Authority to agree on the centralized supply of health products or to set special prescription conditions for certain groups. • Article 7 of Royal Decree-Law 7/2020, of 12 March, allows the Government to set the prices of health products. This option has been developed in Order SND/354/2020 of 19 April. The Resolution that specifies the maximum price of some kind of health products to the public will be published in the next few days. • Article 13 of Royal Decree 463/2020, of 14 March, allows the Minister of Health to conduct temporary requisitions of all types of property. In these cases, the affected parties are entitled to the corresponding compensation.

- Order SND/233/2020, of 15 March, established the duty of companies located in Spain to report, within 2 days, to the competent Health Authorities certain available medical devices (such as masks, gowns, glasses or pcr kits).
- The Sixth Additional Provision of Royal Decree-Law 13/2020, of 7 April, exempts from fees the procedures for the temporary application for licences and the authorisation of the use of products without EC marking mentioned in section Q6.
- Article 3 of Order SND/344/2020, of 13 April, establishes that entities (whether state-owned or privately-owned) must declare to the competent Heath Authorities any device they acquire for the diagnosis of COVID-19 (for example, swabs for sampling, extraction kits or rapid diagnostic tests).
- Order SND/354/2020, of 19 April, mandates that unit sales of surgical masks must be carried out only in pharmacies.

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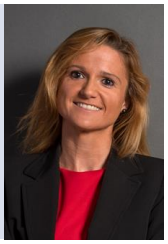

Sweden

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes. However, depending on definitions, the regulating authorities change. Personal protective equipment ("PPE") are generally not medical devices, but are such equipment that must have CE-marking, and thus are regulated and supervised by the Swedish Work Environment Authority ("SWEA"). In most cases, the Swedish Medical Products Agency ("MPA") is the main regulator and supervising authority. The Swedish (emergency) regulations are basically an updated application/registration producer for exceptions regarding Personal protective equipment and some IVDs connected to COVID-19 cases. Due to the COVID-19 pandemic, related *emergency registrations* will be processed with priority. **MD: Personal Protective Equipment exemptions.** In Sweden the Swedish Consumer Agency ("SCA") controls the handling of such equipment for private use, while the SWEA has the equivalent responsibility for personal protective equipment for workplace use. See here. **IVD: Speed-tests and Self-tests.** Self tests, marketed for consumer-use, are prohibited by the Swedish MPA and Speed-tests are still required to have CE-marking, with an opening for exemptions/derogations if application submitted and the MPA convinced. See here.
2	**Do the emergency provisions have an expiry date?**	Yes The decision to approve exemptions for PPEs and IVDs will be temporary and valid until 31 December 2020. Future extensions, after 31 December 202, are very likely, if the coordinating Agency Public Health Agency ("Folkhälsomyndigheten") would make renewed assessment of the risks regarding the threat and new mutations of the new corona-virus.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Yes • Disposable coveralls • Aprons • Gloves • Thicker Gloves • Eye protection, such as visors • Breathing-protection
4	**Do the emergency provisions stipulate which IVDs are included?**	Yes The provisions affect three (3) types of IVDs. 1) Quick/speed-tests, that are *point of care-tests* and are performed by health-care professionals close to the patient, for example at a hospital. This is a different type of IVD than tests that needs to be analysed in a laboratory. 2) Self-tests, are intended to be used by consumers in the home

		environment, unlike #1 above. A self-test is a kit where consumers (layman) in a home environment takes a sample and interprets a test-result themselves. 3) There are also test-products that are used to take a sample at test-subjects home environment, which is then submitted to a healthcare provider or laboratory for analysis. Such products are not considered to constitute self-tests but rather kits for self-sampling, without possibility to read a result. Only 1 and 3 above are included in the emergency guidelines/protocols. Attention! The self-tests (# 2 above) are prohibited by the MPA.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes The Swedish MPA ("Läkemedelsverket") is responsible for ensuring that IVDs comply with the (emergency) terms of their CE-marking, mentioned above, as well as that the unregistered products are not marketed and sold in violations of the current regulations. The Swedish Work Environment Authority ("SWEA") is the responsible authority for checks and controls on the quality of and use of PPEs. The MPA hands over cases to SWEA regarding quality and (temporary) use-registrations of non CE-marked PPEs in (workplace) use. For such PPE being marketed/sold to consumers, the Swedish Consumer Agency ("SCA") performs similar controls.
6	**What are the products exempted from?**	The PPEs are, as mentioned above briefly, exempted from palpable CE-marking requirements otherwise necessary for marketing and sales. It means that companies can apply for a temporary permit to provide PPE which is not CE-marked, only to healthcare providers, emergency services, the Swedish armed forces, the police authority and other such authorities with duty to maintain order in society. For IVDs, there are not exemptions, other that the MPAs window for applications to acquire proportional exemptions for certain COVID-19 related products. Thus, the exemption is not precise, nor does it cover all IVDs. A possible scenario for exemption would probably be the prospect of applying and receiving exemption for certain self-sampling COVID-19 test that can safely be transferred to a secure laboratory.
7	**Are exempted products required to meet GMP?**	No such guideline from the Swedish authorities is given, but the regulators demand that products, even though granted certain exemptions, must meet a reasonable level of protection for user's health and safety.
8	**Are there specific procedures to be followed?**	MDs in general: *Application form of derogations* can be submitted to the MPA or SWEA for prioritized handling-lane at the authority. IVDs exemptions apply only to products to be used Sweden, according to the MPA, but it would probably be accepted as an equivalent exemption at other EU-member states. Such a scenario has probably not been brought up to the CJEU. See relevant links here and here
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes **PPE** • Manufacturer or importer/distributer who wishes to apply for a temporary permit must first contact a notified body to have the product assessed. If the notified body considers that the product meets the basic health and safety requirements, they will issue a temporary certificate to the applicant. Based on the certificate, the manufacturer issues a declaration and produces a user manual before the SWEA can

		issue a temporary permit. **MD & IVDs** • To receive exemptions, as mentioned above, the MPA has to receive an application form of derogations regarding the actual COVID-19 product, for which exemptions are requested.
10	**Are there any additional requirements that must be met for a product to be supplied?**	Yes The Swedish legislation regarding public procurement and anti-corruption, are to be observed carefully, since there are coordinating efforts from effected agencies/regulators, local self-governing regions and other healthcare providers to purchase and control necessary MD and IVDs, and they are producing central instructions for manufacturers/distributors, as we speak. Although the public procurers can support their urgent purchases based on previous existing emergency-previsions, the regulatory landscape is building up very rapidly and it is not advisable for companies to exploit the situations for major sales, without consulting and receiving procurement advice for such possible actions/sales.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes The current regulative body regarding adverse events etc. are intact.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	Yes. The Customs has issued no emergency guidelines for products being imported from non EU-countries. The only concession made is the exemption from the travel ban. Therefore, necessary supplies of food and medicines, for example, should not be affected by the ban.
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	Not immunity, but the decreasing quality of MD and IVDs may create cases of deficient performance of the products, and may lead to injuries. In those cases the regulators cannot punish/fine for something that they themselves have given (temporary) permits and exemptions for.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	SWEA has declared that an employer who uses PPE without CE-marking will not be subject to penalty or fines because of it. The Agency does not carry out inspections, unless there are specific reasons, such as misconducts reported by ombudsman and/or whistleblowing centres etc.

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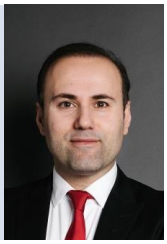

UAE

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	To date (14 April 2020), the Ministry of Health and Prevention ("**MoHaP**") and other concerned government authorities have not issued any guidance/public announcements in respect of the emergency registration of medical devices amid the COVID-19 outbreak in the United Arab Emirates ("**UAE**"). Although the applicable law in the UAE (Federal Law No.8 of 2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions) does not explicitly mention such powers, the MoHaP and government authorities have great discretion and may, from a practical standpoint, authorize the import of unregistered products that are required by health institutions and in emergency situations. MoHaP has informed us that unregistered medical devices may be imported to the UAE, if all of the below conditions are met: • The medical device in question must not be available in the UAE; • A similar alternative medical device with the same purpose and use is not available in the UAE; • A purchase order from a hospital/healthcare facility must be issued and must include the required quantity of such medical device; • The purchasing hospital/healthcare facility must submit a letter to the MoHaP whereby the former confirm their liability and responsibility in respect of the use of the medical device; and • The hospital that requires such medical device must confirm the number of cases/patients which require such device as part of their treatment. However, we have been informed that this authorization to import unregistered medical devices is subject to the MoHaP's approval, which may be granted or denied at their discretion. To clarify, under the current applicable laws in the UAE, being Federal Law No.8 of 2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions, the term "Medical Devices" is broadly defined and also includes IVD's amongst others. No further distinction in the law is made between the import, promotion, registration, distribution, and sale of medical devices and IVD's.
2	**Do the emergency provisions have an expiry date?**	To the extent that the MoHaP has not publicly disclosed any emergency provisions, please refer to the above response whereby we mention that government authorities may, at any moment, enact such legislation or authorize on an ad-hoc basis the import of unregistered medical devices in the UAE. MoHaP could also end such import authorisations.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	N/A
4	**Do the emergency provisions stipulate which IVDs are included?**	The current applicable laws in the UAE do not distinguish between IVD's and other medical devices. The definition of the term "Medical Devices" under the current Federal Law No. No. 8 of 2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions is

		as follows: *"a medical product which contains a material, appliance, instrument, engine, implantable device, detector or system, including: its accessories and software, which achieves the principle purpose action in or on human beings or the animal, without pharmacological, immunological, or metabolic effect, and which is manufactured, sold or offered for use in the following cases:* *1- Diagnosis, treatment, healing, alleviation, monitoring or prevention of a disease, injury or disability;* *2- Investigation, replacement or modification of an anatomy; or* 3- *Control of conception*".
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	From a general standpoint, all medical devices in the UAE must be approved and registered with the MoHaP's Registration Department. However, please refer to our response in Q1 whereby we mention that the MoHaP may approve that unregistered medical devices are imported (if certain conditions are met). In the event that a new legislation is enacted to authorize the import of unregistered products amid the COVID-19 outbreak or a decision to that effect is made, it is likely that such legislation/decision would be taken by the MoHaP.
6	**What are the products exempted from?**	N/A
7	**Are exempted products required to meet GMP?**	N/A
8	**Are there specific procedures to be followed?**	N/A
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	N/A
10	**Are there any additional requirements that must be met for a product to be supplied?**	From a general legal standpoint, in order for a medical device to be traded and marketed in the UAE, the following conditions must be met: • local and foreign manufactures of medical devices must be registered with the MoHaP; • foreign manufacturers of medical devices are required to appoint a local distributor or representative with the required licensed activities; • the prior approval and authorization of the MoHaP must be obtained in order to announce, advertise or promote a medical device; • the information and data inserted on the inner and outer label and the leaflet of the medical device must be similar to the information mentioned on the MoHaP's marketing authorization of the device (meaning that the medical device may only be promoted for the purposes/uses that it was authorised for and as set out on its approved labelling); and • the leaflet must contain information in Arabic or English, except as/when otherwise approved by the MoHaP. These requirements are not exhaustive and at any stage of the

		application, government authorities may request further documents/information.
11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	N/A
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	N/A
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	N/A
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	N/A

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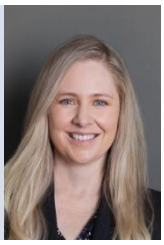

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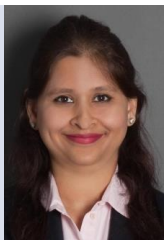

United Kingdom

1	**Did national authorities issue guidance on "emergency registration" and supply of medical devices or IVDs?**	Yes for both certain medical devices (MD) and in-vitro diagnostics (IVDs) for COVID-19. The exemptions contained in Regs 12(5) of the Medical Devices Regulations 2002 (for MDs) and 39(2) (for IVDs) are the main regulatory source which the UK is able to rely upon in order to provide increased regulatory flexibility for the approval of MDs and IVDs during COVID-19. All COVID-19 related queries are being prioritised ahead of standard targets. • MD: Medical devices clinical investigations during the coronavirus (COVID-19) outbreak. • MD: Specification for rapidly manufactured CPAP system to be used during the coronavirus (COVID-19) outbreak. • MD: exemptions from Devices regulations during the coronavirus (COVID-19) outbreak. • MD: specification for ventilators to be used in UK hospitals during the coronavirus (COVID-19) outbreak • IVD: Guidance on coronavirus (COVID-19) tests and testing kits
2	**Do the emergency provisions have an expiry date?**	Not at this stage. The provisions do not have an expiry date per se, but, in certain cases (for example, the exemption pertaining to rapidly manufactured CPAP systems), the exemption can be relied on only during the crisis – this operates as an expiry date practically speaking, but we are not aware of any firm expiry date.
3	**Do the emergency provisions stipulate what type of medical devices are included?**	Again, the guidance has stated the types of MDs and IVDs that are included as part of the exemption to the Medical Devices Regulations 2002. Personal Protective Equipment (PPE), Ventilators, surgical (medical) face masks, examination or surgical gloves, Rapidly Manufactured Continuous Positive Airway Pressure (RMCPAP) – please note that in relation to the RMCPAP, these will not be usable for routine care unless they have been CE marked through the Medical Device Regulations. This also applies to the Rapidly Manufactured Ventilator System (RMVS).
4	**Do the emergency provisions stipulate which IVDs are included?**	Not specifically. The In Vitro Diagnostic Medical Device Regulations (IVDR) do provide a detailed definition of IVDs (without specifying exact types of devices) at Article 2(2) of the IVDR, which applies generally. Please note that this is not an emergency regulation. Exemptions to the existing Regulation can be relied upon in light of COVID-19, but only if an application is put to the MHRA and is approved.
5	**If applicable, do the emergency provisions identify the competent authority that will approve use of/oversee unregistered products?**	Yes, The relevant sub-sectors of the Medicines and Healthcare Products Regulatory Agency (MHRA), dependent on the product. Ventilators require pre-approval from the Department of Health and Social Care (DHSC). New IVD test kits are initially evaluated in a programme coordinated by DHSC and Public Health England. Other government departments have an information-gathering and coordination role. Note: other types of off-label use may be simply at the discretion of a

		healthcare professional, without any prior approval e.g. use of an anaesthesia machine as a (long-term) ventilator: https://www.gov.uk/drug-device-alerts/anaesthetic
6	**What are the products exempted from?**	Face masks can be exempted from meeting the design and safety requirements of the MDR and from being CE marked pre-sale. Gloves can be exempted from the design and safety requirements of the MDR and from being CE marked as MDs pre-sale. PPE; ventilators/RMCPAPs; test kits and other such necessary and urgent MDs and equipment can be exempted from being CE marked in the interest of protection of health and as authorised by the MHRA (where appropriate, in light of specifically adjusted specifications). The above having been said, there is no "automatic" exemption, all exemption applications need to be submitted to the relevant authority before being placed on the market, providing a clinical justification for requesting an exemption.
7	**Are exempted products required to meet GMP?**	MD: products which are exempted from the regulatory requirements are not required to provide evidence that the product meets GMP. IVD: products which are exempted from the regulatory requirements are not required to provide evidence that the product meets GMP.
8	**Are there specific procedures to be followed?**	As noted above, an application must be made to the MHRA (and DHSC for initial approval of ventilators and test kits) if you want to rely on an exemption to the relevant regulations. Please see links in answer to question 1.
9	**Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority prior to being able to be sold/supplied?**	Yes, if applying to MHRA for exemption from the regulations, provide the following information: • details of the product(s) (including model name, description and intended purpose of use) • reasons why the product does not have a valid CE mark • clinical justification for requesting an exemption from the regulations for the product • explanation of any alternative products on the market and reasons why using these products would not be appropriate • numbers of product likely to be supplied under the exemption, plus an indication of how widely used the product is • expected time to gain/re-gain CE certification The MHRA have stated that they do not expect to receive a request for derogation of a CE-marked device where there is limited change to its intended use, but a risk assessment should be carried out and contact made to the notified body for advice in the first instance. When sending the exemption application, MHRA expect the applicant to have evidence that the device performs as intended via performance data for example, such as bench testing and any other study data where applicable.
10	**Are there any additional requirements that must be met for a product to be supplied?**	No – except as included in the MDR/IVDR, and as may be requested from the MHRA pursuant to the initial exemption application on a case by case basis.

11	**Are companies who register medical devices and IVDs under emergency legislative provisions required to meet current regulatory post market obligations such as adverse event reporting and record keeping?**	Yes – nothing has been mentioned that might change the obligations imposed by post-market surveillance requirements. The key obligations here are to ensure the ongoing safety of the device, inform on any developments of future iterations of the device and to conduct Field Safety Corrective Actions (FSCAs). Additionally, there has been no mention of any change to the vigilance requirements. Key obligations are to report serious incidents, conduct voluntary and mandatory reporting and trend reporting. The above applies for both MDs and IVDs.
12	**Are there any additional issues to be addressed with importing unapproved (uncertified) products e.g. customs waivers etc.?**	There are no issues per se, but guidance has been issued on the flexible approaches the UK Government is taking for medicines imported from third countries.
13	**Does the emergency legislative provision for the products, or other legislation, provide "immunity" from or any limitation on liability if the product does not perform its function as stated?**	We are not aware of any specific legislation regarding immunity, but the Government has proposed a contingency fund to cover potential product liability claims against designers and manufacturers of rapidly manufactured equipment in certain circumstances.
14	**Is there any other relevant information related to medical devices and IVDs during this period?**	This area is in constant flux with guidance being regularly issued.

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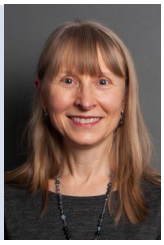

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Through a combination of our strong experience in the life sciences sector and our legal expertise, our mission is to develop both short and long term commercial solutions that will assist you in taking your idea from inception to market place and beyond.

Bird & Bird is a global law firm. Altogether, we have over 1,100 lawyers and legal practitioners working on our clients' issues and business goals worldwide. Our core objective is to select and develop people who possess a rare and invaluable grasp of strategic commercial issues.

By combining this talent with exceptional legal expertise and deep industry knowledge, our advice is always informed, up to date, focused and relevant.

With over 240 experts globally and a wealth of hands-on experience from working inside life sciences companies and regulatory bodies, clients choose us as their strategic partner to guide them through some of their most complex legal challenges.

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