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Communications from Authorities in COVID-19 crisis

03/04/2020

SOURCE	DOCUMENT	DATE	SCOPE	SUMMARY
World Health Organization (WHO)	COVID-19	6-03-2020	Patient management	• The document provides a list of the PPE and MD to be used for each procedure within the health crisis (prevention and management) as well as the regulations and standards applicable.
American Associate for Respiratory Care (AARC)	SARS CoV-2 (Guidance Document)	16-03-2020	Patient management	• Clinical guidance and recommendations on patient management.

European Commission (EC)	COMMISSION RECOMMENDATION (EU) 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat	13-03-2020	MDs & PPEs	• PPEs:
				  • NB under Regulation (EU) 2016/425 shall prioritize the conformity assessments of PPE.
				  • PPE products can follow WHO recommendations instead of harmonized standards, provided that these ensure an adequate level of protection.
				• MDs:
				  • MS can authorize derogations from conformity assessment procedures for MDs.
				• MDs & PPEs:
				  • If market surveillance authorities consider that PPE or MDs ensure an adequate level of health and safety they may authorize the making available of these products on the market even if the conformity assessment procedure is not finished.

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				• PPE or MD not bearing CE marking can be purchased by the relevant MS authorities provided that it is ensured that the products are only available for healthcare workers for the duration of the crisis. • Market surveillance authorities will inform the Commission and the MSs of any temporary arrangement granted to specific PPE or MDs.

European Commission (EC)	Conformity assessment procedures for protective equipment (v.1)	27-03-2020	MDs & PPEs	• Standards:
				  • PPE masks should follow the harmonized standard EN 149:2001+A1:2009.
				  • Surgical masks (MD) should follow harmonized standard EN 14683:2019.
				  • These standards are freely available in the national standardization bodies websites.
				• Conformity Assessment:
				  • The testing can be performed by the manufacturer himself or by a laboratory on his behalf.
				  • For PPE, where the manufacturer follows an alternative standard, an specimen should be tested by a NB.
				  • Surgical masks, examination gloves and some types of gowns are autocertified as Class I MD.

European Commission (EC)	Conformity assessment procedures for 3D printing and 3D printed	30-03-2020	MDs & PPEs (*3D Printing*)	• 3D printing machinery must follow harmonized standards.

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	products to be used in a medical context for COVID-19			• 3D printed products may be qualified as MDs depending on their intended purpose. If so, they must fulfil Directive 93/42/EEC (MDD). • Accessories of MDs qualify as devices and shall meet the corresponding requirements of the MDD. • 3D printed plastic valves used in respiratory ventilators may qualify either as accessories or as parts and components. • Material used for 3D printing should be tested for the purpose of the printed product and its final use.
European Commission (EC)	Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.)	30-03-2020	Biocides	• Products cleaning the skin are likely subject to the EU Cosmetic Products Regulation (1223/2009). • If no main purpose is declared and the product contains an active substance and marketed with claims of biocidal activity, probably subject to the EU Biocidal Products Regulation (528/2012).

Medicines and Healthcare products Regulatory Agency (MHRA)	Rapidly Manufactured Ventilator System (v.3.1)	26-03-2020	MDs (*Ventilators*)	• Minimum specifications for ventilators:
				  • Technical requirements for RM ventilators.
				  • Gas supply and electrical supply requirements, acc. EN ISO 5359:2014+A1:2017, ISO 5359:2014/AMD 1:2017, BS 2050:1978, IEC 60601 and IEC 62353)
				  • Measures for infection control & cleaning of the device.
				  • Monitoring and alarms systems requirements, acc. IEC 60601-1-8:2006.
				  • Biological safety requirements, acc. ISO 18562-1:2017.

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				• Software safety requirements (Appendix C). • Indications for testing: • Full compliance to ISO 80601-2-12:2020 is not requested but essential safety standards must be met. • Usability testing requirements, acc. ISO 62366
Spanish Government, Official State Gazette (BOE)	Resolución de 20 de marzo de 2020, de la Secretaría General de Industria y de la Pequeña y Mediana Empresa, sobre especificaciones alternativas a las mascarillas EPI con marcado CE europeo.	20-03-2020	PPEs (*Masks*)	• Four different scenarios: 1) PPE Masks CE marked acc. to harmonized standards (EN 149:2001+A1). 2) Public acquisition of PPE Masks without CE marking but compliant with alternative standards (*). 3) Temporary exemption of CE marking if authorized by competent Health Authority and conformity assessment process has been initiated. • Alternative standards accepted: • (*) NIOSH_USA & KN95_China
Spanish Government, Ministry of Health & AEMPS	Información sobre prototipos de respiradores. Pruebas de seguridad y requisitos de investigación clínica	27-03-2020	MDs (*Ventilators*)	• Use of non-CE marked RM Ventilators on patients only allowed in the context of a Clinical Investigation (CI). Steps: 1) Following technical documentation shall be sent to pscontrol@aemps.es: • Technical specifications and design, including diagrams, pictures, IFUs and labelling. • Identification of similar devices already marketed and degree of equivalence.

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				• Brief Risk Analysis • ER checklist • Description of the manufacturing process and controls. • Results of preclinical testing: ✓ Testing in human models (artificial lung or patient simulator), ✓ Validation result in pig model, ✓ Safety testing acc. ISO 60601-2-12, ISO 80601-1, EN 794-3 and/or guidance documents of health authorities (MHRA, WHO, AARC – see above). 2) Taxes shall be paid to AEMPS (code 8.19) and CI authorization requests must be submitted to psinvclinic@aemps.es, with the following information: • Administrative data: title of the investigation, centers involved, contact details, name of the sponsor, data of the entity responsible of organizing the clinical investigation and data of the Principal Investigator. • Approval of the ethics committee and conformity of the centers involved for the management of the CI. • Conformity of AEMPS with the preclinical and technical documentation. • Investigation protocol with minimum set of data, signed by the Principal Investigator.

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Spanish Government, Ministry of Industry, Trade and Tourism	Marcado CE de las mascarillas filtrantes de protección contra partículas (Equipos de Protección Individual, EPI) (v.2)	02-04-2020	PPEs (*Masks*)	• PPE masks should follow harmonized standard EN 149:2001+A1:2009.
				• PPE masks are Category III PPE.
				• The CE marking process for Category III PPE consists of:
				  • EU type evaluation of the device by a NB by evaluation of the Technical Documentation and a specimen.
				  • Conformity to type according Annex VII or VIII of Regulation 2016/425.
				  • Draw up of the Declaration of Conformity.

Spanish Government, Ministry of Industry, Trade and Tourism	Protección ocular y facial: gafas de protección y pantallas faciales (Equipos de Protección Individual, EPI) (v.1)	02-04-2020	PPEs (*Goggles & Facial Shields*)	• PPE for eye protection should follow harmonized standard EN 166:2002
				• PPE goggles and Facial shields are mainly Category II PPE.
				• The CE marking process for Category II PPE consists of:
				  • EU type evaluation of the device by a NB by evaluation of the Technical Documentation and a specimen.
				  • Conformity to type according Annex VI of Regulation 2016/425.
				  • Draw up of the Declaration of Conformity.

Spanish Government, Ministry of Industry, Trade and Tourism	Ropa de protección (Equipos de Protección Individual, EPI) y batas quirúrgicas (Producto Sanitario, PS) (v.1.1)	01-04-2020	MDs & PPEs (*Gowns*)	• PPE
				  • PPE Gowns should follow harmonized standards EN 14126:2004 and 14605:2005+A1:2009
				  • PPE gowns are Category III PPE.
				  • The CE marking process for Category III PPE consists of:

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				• EU type evaluation of the device by a NB by evaluation of the Technical Documentation and a specimen. • Conformity to type according Annex VII or VIII of Regulation 2016/425. • Draw up of the Declaration of Conformity. • MD • MD Gowns should follow harmonized standards EN 13795-1:2020 and EN 13795-2:2020 • MD Gowns are Class I devices. • Class I MDs are autocertified.
Spanish Government, Ministry of Industry, Trade and Tourism	Marcado CE de las mascarillas quirúrgicas (Producto Sanitario, PS) (v.2)	01-04-2020	MDs (*Surgical Masks*)	• Surgical masks are Class I MDs, autocertified and should follow harmonized standard EN 14683:2019+AC and ISO 22609 (if applicable). • Operating License: • Manufacturers located in Spain shall have an operating license (*Licencia Previa de Funcionamiento)*. • This license can be requested to AEMPS through a portal (https://fabricaps.aemps.es/fabricps/faces/login.xhtml), by providing the basic documentation on the facilities, quality management system and the reports of product compliance with the relevant standards. Requests shall be processed with urgency. • Temporary CE mark exemptions:

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				• An express authorization will be required to market products without CE marking. • To obtain such authorization, the manufacturer will have to send a report of product compliance with relevant standards EN 14683 (and ISO 22609 if applicable), the IFUs, labelling and technical specifications to pscontrol@aemps.es.

General Council of Catalonia	Importació de productes sanitaris durant el període d'alerta del coronavirus	27-03-2020	MDs (Import)	• Technical specifications and administrative data to be supplied for MD import.
				• Import process for entities without importing license in Spain, depending on entity:
				  • Companies:
				  1) Contact AEMPS with details on the MD to import (pscontrol@aemps.es).
				  2) AEMPS authorizes the import and this is managed by the company.
				  3) The importer company provides the technical specifications and the administrative data to the freight forwarder.
				  • Hospitals or public health entities:
				  1) The legal representative prepares a written declaration on the MD to import, along with the categorization of the product, amount, intended use and the CE DoC.
				  2) A freight forwarder handles the importation

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				3) The importer hospital provides the technical specifications and the administrative data to the freight forwarder.
General Council of Catalonia	Principals requeriments d'homologació i certificació del material necessari per combatre la Covid-19	27-03-2020	MDs & PPEs (Requirements)	• Spanish manufacturers need to possess an operating license for placing MDs on the market. • In principle, MDs and PPEs placed on the market shall bear the CE marking. • For exemption of CE marking of ventilators, AEMPS should be addressed (sgps@aemps.es). • For certain PPEs there are exemptions of CE marking as listed in the BOE of 20 March 2020 (see above). • PPE Gowns shall comply with EN 14126:2004