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Notice to third country manufacturers of SARS-CoV-2 *in vitro* diagnostic medical devices

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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Scope

This notice is addressed to manufacturers of *in vitro* diagnostic medical devices (IVDs) with the intended purpose to detect and/or quantify markers of SARS-CoV-2 infection[1] who are based in countries outside the EU or the EEA and who place or intend to place the abovementioned devices on the EU market. It is intended to highlight a number of common issues that EU national competent authorities have identified in the course of their market surveillance activities regarding compliance of SARS-CoV-2 IVDs with the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices. These issues can also be relevant for SARS-CoV-2 devices which are transitioning to Regulation (EU) 2017/746 (also see last paragraph).

Guidance documents relevant for SARS-CoV-2 IVDs are available on the European Commission's medical devices webpage: https://ec.europa.eu/health/md_sector/new_regulations/guidance_en. Basic guidance on conformity assessment of SARS-CoV-2 devices under Directive 98/79/EC in the European Commission's dedicated Q&A document: https://ec.europa.eu/health/sites/default/files/md_sector/docs/covid-19_ivd-qa_en.pdf

Designation of an authorised representative

A manufacturer who does not have a registered place of business in an EU Member State and who intends to place devices on the EU market under his own name must designate an EU authorised representative in accordance with Article 10(3) of Directive 98/79/EC. That authorised representative is responsible for the notification required by Article 10(1) of Directive 98/79/EC. It should be noted that it is required to designate only one authorised representative and to notify only the competent authority where the authorised representative is established.

Involvement of a notified body for self-tests under Directive 98/79/EC

Under Directive 98/79/EC, SARS-CoV-2 IVDs intended to be used by professionals do not need assessment by a notified body. In contrast, for SARS-CoV-2 self-tests, i.e. those intended for lay users, the manufacturer must lodge an application with a notified body (see procedures referred to in the second subparagraph of Article 9(1) of Directive 98/79/EC). A list of notified bodies designated under Directive 98/79/EC is available on the NANDO database: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20

[1] I.e. presence of and/or exposure to SARS-CoV-2

Translations of the instructions for use and the label

The instructions for use and the label are key documents accompanying the device to inform the user about the correct use, safety and performance of the device. There may be national requirements regarding the languages in which these documents are supplied (see Article 4(4) of Directive 98/79/EC). Manufacturers must ensure good quality of translations of the instructions for use and of the text elements of the label into all languages required by the Member States where the device is made available. Especially for self-tests, manufacturers must ensure that the instructions for use and the text elements of the label include a good-quality translation into the official language(s) of the Member State in which the device for self-testing reaches its final user (section 8.1 of Annex I of Directive 98/79/EC).

Guidance on performance evaluation of SARS-CoV-2 IVDs

The Medical Device Coordination Group document MDCG 2021-21 provides guidance on the performance evaluation of different types of SARS-CoV-2 IVDs, including SARS-CoV-2 self-tests: https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-21_en.pdf This document is relevant for devices being placed on the market under Directive 98/79/EC and under Regulation (EU) 2017/746.

Transition to Regulation (EU) 2017/746

Under Regulation (EU) 2017/746, all SARS-CoV-2 IVDs are subject to conformity assessment involving a notified body. Manufacturers that wish to place devices on the market in accordance with Regulation (EU) 2017/746, whether based in the EU/EEA or in 3rd countries, that have not yet submitted an application for conformity assessment to a notified body are strongly encouraged to liaise with designated notified bodies as soon as possible. You may find the list of notified bodies designated under Regulation (EU) 2017/746 on the NANDO database: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35. A good quality of the documentation prepared by the manufacturer will facilitate the assessment by the notified body. Please note also the obligations to designate an authorised representative established in the EU in accordance with Article 11 of Regulation (EU) 2017/746.

Provision of the instructions for use and label in the official Union language(s) determined by the Member State in which the device is made available to the user or patient is required by Article 10(10) of Regulation (EU) 2017/746.

See also Article 16(2), (3) and (4) of the Regulation (EU) 2017/746 and related guidance MDCG 2021-26 on the role of importers, distributors or other persons that engage in repackaging and relabeling activities, including translation of the information supplied by the manufacturer.

In line with Article 110(3) of Regulation (EU) 2017/746, SARS-CoV-2 self-tests with valid certificates issued in accordance with Directive 98/79/EC may continue to be placed on the market after the date of application of Regulation (EU) 2017/746, provided they continue to comply with the requirements of the Directive, that there are no significant changes in the design or intended purpose, and that they comply with the requirements of Regulation (EU) 2017/746 on post-market surveillance, vigilance and registration of economic operators and of devices that replace the corresponding requirements of the Directive. [2]

[2] On 14 October 2021, the European Commission made a proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices (COM(2021)627 final). It contains a proposed provision that would enable SARS-CoV-2 IVDs placed on the market with a declaration of conformity, regardless of whether or not they also have a notified body certificate, to be subject to the transitional provisions in Art. 110(3).