NOTIFICATION

Addendum

The following communication, dated 18 February 2022, is being circulated at the request of the delegation of Switzerland.

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**Title:** Draft ordinance on in-vitro diagnostics

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| **Reason for Addendum:** |
| [  ] | Comment period changed - date:  |
| [  ] | Notified measure adopted - date:  |
| [  ] | Notified measure published - date:  |
| [  ] | Notified measure enters into force - date:  |
| [  ] | Text of final measure available from[[1]](#footnote-1):  |
| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [X] | Content or scope of notified measure changed and text available from1: The final version of the new Swiss In vitro Diagnostic Medical Devices Ordinance (IvDO) will be available on the following website: <https://www.fedlex.admin.ch/en/home?news_period=last_day&news_pageNb=1&news_order=desc&news_itemsPerPage=10> New deadline for comments (if applicable): 30 days from notification |
| [  ] | Interpretive guidance issued and text available from1:  |
| [  ] | Other:  |

**Description:** Content of changed notified measures are summarized as follows:

**Adjustments due to the lack of update of Chapter 4 of the Switzerland-EU MRA**

The Mutual Recognition Agreement on conformity assessment between Switzerland and the European Union (Switzerland-EU MRA) guarantees the market access in the sector of medical devices (Annex 1, Chapter 4 of the MRA) between Switzerland and the EU. The MRA is based on the equivalence of the legislation between Switzerland and the EU. The draft of the new Swiss In vitro Diagnostic Medical Devices Ordinance (IvDO) is therefore equivalent to the new EU In vitro Diagnostic Medical Devices Regulation (IVDR). The IvDO draft was notified to the Committee on Technical Barriers to Trade (TBT Committee) of the WTO on the 21st of June 2021 parallel to the public consultation procedure. The IvDO is foreseen to enter into force on the 26th of May 2022.

In order for the mutual recognition elements between Switzerland and the EU under the MRA to apply to the new in vitro legislation, Chapter 4 on medical devices of the Agreement should be updated to reflect the upcoming entry into force of the new Swiss IvDO and of the EU IVDR on 26 May 2022. This said, due to political reasons, Chapter 4 of the MRA could not be updated on 26 May 2021, when the new Swiss Medical Ordinance (MedDO) entered into force simultaneously with the EU MDR. As a result, the access to the central European database EUDAMED is denied to the Swiss authorities and there is a lack of cooperation with the EU in market surveillance. Without an update of the MRA on 26 May 2022, transitional measures similar to those implemented and communicated for the Swiss MedDO to mitigate these and other negative effects resulting from this situation are foreseen in the new Swiss IvDO. These include deadlines for the appointment of an authorized representative in Switzerland.

The main adjustments notified under the Addendum are the following:

* Recognition by Switzerland of certificates issued by a notified body designated under EU law and established in an EU or EEA state;
* Transitional periods for the appointment of an authorized representative in Switzerland for manufacturers based in the EU or EEA and for manufacturers with an authorized representative in the EU, depending on the product classification;
* Additional flexibilities for labeling requirements for the Swiss authorized representative and the importer within the scope of tolerance in enforcement of the MedDO will apply equally for the IvDO;
* Due to the denial of access to EUDAMED, the following main adjustments are foreseen:
	+ References to EUDAMED are deleted and replaced where necessary by notifications to Swissmedic;
	+ Swiss economic operators must register the required information according to Annex VI EU-IVDR with Swissmedic within a defined period of time;
	+ Manufacturers report serious incidents and safety corrective measures in the field to Swissmedic.

**Progressive roll-out of the IvDO**

There is a serious shortage of notified body capacity, making it impossible for manufacturers to conduct the legally required conformity assessment procedures in time. Without legislative actions, there would be a risk of significant disruption in the supply of various essential in vitro diagnostic medical devices on the market. This would affect the diagnosis of patients and their access to relevant health care. Therefore, Switzerland has decided to introduce a progressive roll-out of the Swiss IvDO similar to that of the EU.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)