EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
DIRECTORATE-GENERAL FOR TRADE

The Directors-General

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NOTICE TO STAKEHOLDERS: STATUS OF THE EU-SWITZERLAND MUTUAL RECOGNITION AGREEMENT (MRA) FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

Until now, Switzerland has been participating in the European Union internal market for *in vitro* diagnostic medical devices through the medical devices chapter of the EU-Switzerland Mutual Recognition Agreement (MRA). The medical devices chapter of the MRA has provided for recognition of conformity assessment certificates between the European Union and Switzerland based on equivalence of Directive 98/79/EC on *in vitro* diagnostic medical devices and the corresponding Swiss legislation. This has facilitated seamless trade of *in vitro* diagnostic medical devices between the parties.

The new Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices becomes applicable on 26 May 2022[1], replacing Directive 98/79/EC. In the absence of an update of the MRA to include Regulation (EU) 2017/746, the part of the MRA chapter covering *in vitro* diagnostic medical devices ceases to apply as of 26 May 2022[2].

As a result, the trade facilitating effects of the MRA for *in vitro* diagnostic medical devices, including the mutual recognition of conformity assessment results, the absence of the need for an authorised representative and the alignment of technical regulations, cease to apply as of that date.

Therefore, stakeholders should note the following consequences as of 26 May 2022:

- For all new *in vitro* diagnostic medical devices, Swiss manufacturers will be treated as any other third country manufacturer intending to place its devices on the EU market. In particular, *in vitro* diagnostic medical devices of Swiss

[1] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OF L 117, 5.5.2017, p. 176), amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices(OJ L 19, 28.1.2022, p. 3).

[2] See also "Notice to stakeholders: Status of the EU-Switzerland Mutual Recognition Agreement (MRA) for Medical Devices" published by the Commission on 26 May 2021.

manufacturers requiring certification on the basis of a conformity assessment procedure must be certified by conformity assessment bodies established within the EU.

- Certificates issued under the MRA by conformity assessment bodies established in Switzerland will no longer be recognised as valid in the EU[3] even if they were issued before 26 May 2022.

- For *in vitro* diagnostic medical devices placed on the market after 26 May 2022, Swiss manufacturers and third country manufacturers whose authorised representative was previously established in Switzerland must designate an authorised representative established in the EU.

Accordingly, affected stakeholders (e.g. manufacturers, EU importers and distributors, authorised representatives) are required to act in accordance with the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, noting in particular:

- the requirements for economic operators including the need to appoint an EU authorised representatives,

- the requirements on registration and labelling of products.

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[3] Please note that since 2015 there is not any Swiss conformity assessment body designated under the Directive 98/79/EC on *in vitro* diagnostic medical devices.