NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Switzerland **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Federal Office of Public Health**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** State Secretariat for Economic Affairs SECOHolzikofenweg 36, 3003 Berntbt@seco.admin.ch, [www.seco.admin.ch](http://www.seco.admin.ch) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** In vitro diagnostic medical devices; In vitro diagnostic test systems (ICS 11.100.10) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft ordinance on in-vitro diagnostics (52 page(s), in German; 51 page(s), in French; 50 page(s), in Italian) |
| **6.** | **Description of content:** On April 5, 2017, the Parliament and the Council of the European Union adopted the new Medical Devices Regulation (MDR) and In-vitro Diagnostics Regulation (IVDR). By aligning Swiss medical device legislation with the two EU regulations, the safety and quality of medical devices, including in vitro diagnostics, should also be improved in Switzerland ensuring better protection of patients. In this regulation, the provisions of the EU-IVDR have been transferred into a new Swiss regulation on in vitro diagnostic medical devices. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Harmonization with EU-IVDR, Improve safety and quality of In-vitro diagnostic medical devices for better patient protection.; Protection of human health or safety; Harmonization |
| **8.** | **Relevant documents:** More information on the revision of the Medical Devices legislation: [Revision of medical devices legislation (admin.ch)](https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/revision-med-prod-verord-mepv.html)  |
| **9.** | **Proposed date of adoption:** 20 April 2022**Proposed date of entry into force:** 26 May 2022 |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** Swiss Information Center for Technical Rules (switec)Sulzerallee 708404 Winterthur8400+(41) 52 224 54 55+(41) 52 224 54 75 (Fax)switec@snv.ch<https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/heilmittel/meprrevision/ivdv-vl-apr2021.pdf.download.pdf/IvDV_DE.pdf><https://www.bag.admin.ch/dam/bag/fr/dokumente/biomed/heilmittel/meprrevision/ivdv-vl-apr2021.pdf.download.pdf/ODiv_FR.pdf><https://www.bag.admin.ch/dam/bag/it/dokumente/biomed/heilmittel/meprrevision/ivdv-vl-apr2021.pdf.download.pdf/ODiv_IT.pdf> |