

# Support from the medical technology industry for the ongoing EU-Switzerland negotiations

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Switzerland is situated at the heart of Europe and has a long standing economic, cultural and societal integration with the European Union. The EU is Switzerland's most important trading partner. For the EU, Switzerland is the fourth most important trading partner.

Since the Free Trade Agreement of 1972 between Switzerland and the EU, an increasingly dense network of around 20 main agreements in critical sectors including medical devices and *in vitro* diagnostic medical devices (IVDs) has been concluded in stages (Bilaterals I and II). On 26 May 2021, when the Swiss government broke off the negotiations for an institutional agreement intended to streamline and stabilize the numerous bilateral agreements, the EU declared the existing MRA (Mutual Recognition Agreement) for medical devices no longer applicable and downgraded Switzerland to a third country, effectively stopping the privileged trade in the area of medical devices with immediate effect. A similar situation has also been applying to IVDs as of 24 May 2022.

Swiss Medtech, SVDI and MedTech Europe, the Swiss and European medical technology industry associations, stand united behind the resumption of the EU-Switzerland negotiations in spring 2024 to secure an ambitious bilateral agreement («3rd bilateral package»). **The update of the MRA in relation to conformity assessments for medical devices and IVDs is long overdue and should represent a key objective of the ongoing negotiations.** It is in the mutual interest of Switzerland and the European Union: medical care for Swiss and European patients would be in a much better position with a timely adoption of an efficient, trade facilitating 3rd bilateral package.

Industry stands ready to engage with the Swiss and EU counterparts and would like to offer its perspective on the main aspects that should be considered during the negotiation phase, which are the following:

**Full access for patients to life-enhancing and -supporting medical technologies.** Policies need to ensure equitable access to top-tier healthcare for all patients in Europe, foster a unified digital health ecosystem, build resilient healthcare systems capable of withstanding future crises, and establish healthcare systems that are financially and environmentally sustainable. Any barrier between Switzerland and the EU hampers this goal on both sides of the borders for it diminishes the access of patients to medical devices and IVDs. On the contrary, the update of the MRA would accelerate the flow of innovative products between Switzerland and the EU.

**Unobstructed trade of medical technologies between Switzerland and the EU.** The vision of the EU common market is a fully functioning, streamlined single market that facilitates free movement, boosts investment and supports innovation. The import and the export of medical technology products from and to Switzerland by EU countries is not insignificant and accounts for up to 8% of the total volume of individual countries. The missing update of the MRA for medical devices and IVDs has led to a series of new obstacles for import and

export, ranging from labelling requirements to the establishment of Authorised Representatives in Switzerland for EU companies and vice versa. This stands in contrast with the vision of the common market. Market opportunities in Europe can only be fully exploited if barriers to the free movement of goods, people, services, capital and data are removed.

**Elimination of administrative hurdles for the medtech industry.** The missing MRA update leads to annual recurring cost of approximately EUR 100 million in the EU for the establishment of the European representatives (EC-REP) and EUR 200 million in Switzerland for the Swiss representatives (CH-REP) and to comply with the related country-specific labelling requirements. These costs are purely for administrative reasons, and do not improve the quality of the medical devices or the care delivered to the patients, but rather they endanger it: for example, due to these challenges, 25% of manufacturers chose not to establish a CH-REP, leading to a loss of 15% of imported medical devices in Switzerland.

**Strengthening competitiveness.** As highlighted during the EU Council Meeting of 19 April 2024, cooperation with like-minded partners in business, research and production remains vital for the EU. The stable relations between Switzerland and the EU and a reduction of the current market access restrictions would critically support investment in joint projects and boost collaboration in key areas including medical technology, a strategic sector that is already positively contributing to the trade balance of both sides.

Maintaining the current situation, with no MRA in place between Switzerland and Europe in the medical technology sector, creates an increasingly challenging environment for businesses to operate, is having an adverse impact on the competitiveness of the European and Swiss medtech industry and the attractiveness of the European market, and ultimately negatively affects patients' timely access to safe and innovative medical devices.



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## About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

[www.medtecheurope.org](http://www.medtecheurope.org).

## About Swiss Medtech

Swiss Medtech is the industry association for Swiss medical technology and represents over 800 members. With 71,700 employees and a contribution of 11.9% to Switzerland's positive trade balance, medical technology is an economically significant sector. Swiss Medtech advocates an environment in which medical technology can deliver top performance in favour of first-class medical care.

[www.swiss-medtech.ch](http://www.swiss-medtech.ch)

## About SVDI

SVDI is a trade association consisting of members of the Swiss diagnostics industry. SVDI plays an active role in the economic and political environment of the healthcare sector and is responsible for supporting its member companies.

[www.svdi.ch](http://www.svdi.ch)

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