SWISS MEDTECH

CH comme état tiers: Effet sur les fabricants, importateurs et distributeurs dans le domaine de la réhabilitation

05.07.2021

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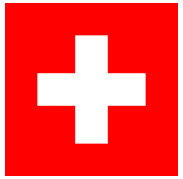
La Suisse et RDM

- **MDR** regulates placing of products on the EU internal market
  → EU market access for companies worldwide
- **MedDO** = Medical Devices Ordinance (equivalent to MDR)
  → CH Market access for companies worldwide
- **MRA** = Mutual Recognition Agreement Agreement on the elimination of technical barriers to trade CH-EU
  → Privileged EU market access for CH companies
- **InstA** = Institutional Framework Agreement
  → Regulates automatic adoption of EU legal decisions for CH



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Without MRA

With MRA

Situation for Swiss Medtech Industry

→ No InstA

→ No update of the MRA

→ CH becomes third country to EU (need for AR)

InstA: Institutional Agreement EU-CH
MRA: Mutual Recognition Agreement EU-CH
AR: Authorised Representative

Interview with Federal Council Parmelin on 26.05.2021

Why are ARs needed?

EU market access for medical devices (MD) of third countries

- No access to mutual assistance of authorities
- Need for representative of legal manufacturer in EU for market surveillance, vigilance and product liability issues

→ Need for authorised representative in EU

Swiss Authorities: Weighing up of interests must be ensured

- Equivalence to EU (MDR)
- Product safety
- Security of supply
- Enforceability (product liability)

→ Need for authorised representative in CH

Balancing of Goods: at what Cost?

Equivalency to EU Law

Safety of Medical Device

Third country status

Enforceability

Security of Supply

+ 8% cost of MD due to MDR

[Source: SMTI, Sept. 2020]

+ 2% cost for exported MD (EAR)

+ 2-10% cost for imported MD (Swiss AR)

[Source: SMT surveys from March 2020 and Nov. 2020]

+ x% cost for substitution MD (Swiss AR)

Cost of medical devices: 12B CHF (14% of total health cost of 85B CHF)
Cost increase of medical devices by 10% → Increase in total costs by 1.4%

Status MRA

- 31.03.2021: Offer for “small” amendment by EU commission
- Several rounds of negotiations between SECO and EU COM
- 26.05.2021: Agreement reached at 2 PM

- **Outcome:**
  unsure

From : DG SANTE B6 Medical Devices & DG TRADE — **31 March 2021**

The Commission services would like to inform that, to mitigate the risk of possible disruptions of supply of medical devices on the EU market, and to provide legal certainty to companies, the European Union will propose to Switzerland a limited modification to the current Mutual Recognition Agreement. An amendment is currently under preparation, aimed at granting certificates already issued in Switzerland for existing medical devices under the Swiss legislation equivalent to existing EU Directives the same transitional validity as the new EU Medical Devices Regulation grants to certificates issued in the EU.

Switzerland ends talks on EU partnership

The European Commission warned the decision will erode EU-Swiss relations.

What now?

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- Legal view of EU commission
- Does not correspond to Swiss point of view

→ No regulatory certainty!
→ No access to EUDAMED for Swissmedic!

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical devices, Health Technology Assessment

Brussels, 26 May 2021

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

The following consequences as of 26 May 2021 should therefore be noted by stakeholders:

- For all new devices, Swiss manufacturers will be treated as any other third country manufacturer intending to place their devices on the EU market. In particular, new Swiss medium and high-risk devices must be certified by conformity assessment bodies established within the EU.
- Existing certificates issued under the MRA by conformity assessment bodies established in Switzerland will no longer be recognised as valid in the EU.
- For existing certificates issued under the MRA by conformity assessment bodies established in the EU, Swiss manufacturers and third country manufacturers whose authorised representative was previously established in Switzerland, must designate an authorised representative established in the EU.

European Commission

EUDAMED
European database on medical devices

ACTOR MODULE FAQs
June 2021 v1.3

1.3 Are Swiss national competent authorities registered in the EUDAMED Actor module?

No, the Swiss national competent authority is not registered in EUDAMED as there is no longer a mutual recognition agreement between the EU and Switzerland for medical devices as of 26 May 2021. Switzerland is therefore considered as a non-EU country.

Status MedDO

- Equivalent to MDR
- Transition period as compromise between Swiss authorities and Swiss industry
- Amendment published on 19 May 2021 (1 week before DoA of MDR)

Art. 104*a*[98] Désignation d'un mandataire

[1] Si le fabricant a son siège dans un État de l'UE ou de l'EEE ou s'il a mandaté une personne ayant son siège dans un État de l'UE ou de l'EEE, il est tenu, pour tous les dispositifs mis sur le marché après le 26 mai 2021, de désigner un mandataire conformément à l'art. 51, al. 1, dans les délais suivants:

a. pour les dispositifs de classe III, les dispositifs implantables de classe IIb et les dispositifs médicaux implantables actifs: jusqu'au 31 décembre 2021;

b. pour les dispositifs de classe IIb non implantables et les dispositifs de classe IIa: jusqu'au 31 mars 2022;

c. pour les dispositifs de classe I: jusqu'au 31 juillet 2022.

[2] Concernant les systèmes et les nécessaires, le mandataire visé à l'art. 51, al. 5, doit être désigné d'ici au 31 juillet 2022.

What is your role?

Economic operators acc. MDR

- Manufacturer
- Authorised Representative
- Importer
- Distributor

Article 16

Cas dans lesquels les obligations des fabricants s'appliquent aux importateurs, aux distributeurs ou à d'autres personnes

1. Un distributeur, un importateur ou une autre personne physique ou morale s'acquitte des obligations incombant aux fabricants s'il procède à l'une des tâches suivantes:

c) modifier un dispositif déjà mis sur le marché ou mis en service d'une manière telle que cela peut influer sur la conformité avec les exigences applicables.

Le premier alinéa ne s'applique pas aux personnes qui, sans être considérées comme des fabricants au sens de l'article 2, point 30), assemblent un dispositif déjà sur le marché ou l'adaptent à l'intention d'un patient donné sans en modifier la destination.

CH-REP acc. MedDO

swissmedic

Aide-mémoire
Mandataire suisse

3.1 Mention du mandataire suisse sur l'emballage

Le mandataire suisse doit être mentionné sur l'emballage (« étiquetage du dispositif ») selon l'annexe I, ch. 23.2, let. d) du RDM. La mention du mandataire suisse sur le dispositif proprement dit, sur le mode d'emploi selon l'annexe I, ch. 23.4, let. a) RDM ainsi que sur les documents joints au dispositif (bon de livraison, facture commerciale) n'est pas obligatoire.

3.2 Utilisation du symbole « CH REP » sur l'emballage

Le nom et l'adresse du mandataire doivent être mentionnés à proximité directe du symbole. L'adresse doit permettre de prendre contact avec le mandataire suisse. Mentionner exclusivement la case postale, une adresse e-mail ou un numéro de téléphone n'est pas suffisant.

Nom et adresse de la succursale enregistrée du mandataire

- https://www.swissmedic.ch/swissmedic/fr/home/dispositifs-medicaux/acces-au-marche/ch-rep.html

Übersicht der Fristen für Medizinprodukte

Handlungspflicht	Gesetzliche Grundlage		Fristen			
	MepV	EU-MDR	Klasse IIb implantierbar + Klasse III	Klasse IIa + Klasse IIb	Klasse I	Systeme und Behandlungseinheiten [MDR Art. 22]
Angabe des Importeurs auf Produkt oder Verpackung oder dem Produkt beiliegenden Dokument	MepV Art. 53 Abs. 2	MDR Art. 13 Abs. 3	ab dem 26.05.2021			
Einrichten eines **CH-Bevollmächtigten**	MepV Art. 51 Abs. 1, resp. Abs. 5 für SPPP; Übergangsfristen gemäss Art. 104a*	--	31.12.2021	31.03.2022	31.07.2022	31.07.2022
Einrichten eines **EU-Bevollmächtigten**	--	MDR Art. 11 (min. für eine generische Produktegruppe)	ab dem 26.05.2021			
Registrierung der **Wirtschaftsakteure bei Swissmedic ("CHRN")**	Inverkehrbringen von **MDD/ AIMDD / MDR** Produkten **nach** dem 26.05.2021: MepV Art. 55 Abs. 1, resp. Abs. 5 für SPPP	--	3 Monate seit dem ersten Inverkehrbringen			
Hersteller (inkl. System und Behandlungseinheiten), Bevollmächtigte und Importeure, mit Sitz in der Schweiz	Inverkehrbringen von **MDR** Produkten **vor** dem 26.05.2021: "Nachregistrierung" gem. MepV Art. 104b	--	innert 6 Monaten (bis am 26.11.2021)			

* Pflicht gilt per 26.05.2021. Übergangsfristen gelten nur für EU/EWR Hersteller oder Drittstaathersteller mit EU/EWR-REP.

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Registrierung der **Wirtschaftsakteure in EUDAMED**	--	MDR Art. 31, resp. MDR Art. 123 Abs. 3 Bst. d)	6 Monaten nach Veröffentlichung der Bekanntmachung			--
Zuteilung / Erstellung einer UDI	MepV Art. 17 Abs. 1	MDR Art. 27 Abs. 3	vor dem Inverkehrbringen			
UDI-Datenträger auf der Kennzeichnung des Produktes	MepV Art. 17 Abs. 2, 4, wie in Übergangsbestimmungen Art. 104	MDR Art. 123 Abs. 3 Bst. f, MDR Art. 27 Abs. 4	26.05.2021	26.05.2023	26.05.2025	noch ungeklärt
UDI-Datenträger auf dem Produkt selbst anbringen	MepV Art. 17 Abs. 4, wie in Übergangsbestimmungen Art. 104	MDR Art. 123 Abs. 3 Bst. g, MDR Art. 27 Abs. 4	26.05.2023	26.05.2025	26.05.2027	--
Produktregistrierung bei Swissmedic	MepV Art. 17 Abs. 5, wie in Übergangsbestimmungen Art. 110 Abs. 2	--	tritt zu einen späteren Zeitpunkt in Kraft			
	Nachmeldung gem. MepV Art. 108 Abs. 2		6 Monate nach Inkrafttreten des Art. 17 Abs. 5			
Produkteregistrierung in EUDAMED3	--	MDR Art. 29 Abs. 4: sechs, resp. 18 Monate nach "go live"	tritt zu einen späteren Zeitpunkt in Kraft			

Problems for CH as Third Country to EU

Equivalency to EU regulations (MedDO & IvDO):

- Amended MedDO generates uncertainties
  → over 500 enquiries at SMT, over 1000 at Swissmedic
  → need urgent clarification of open questions (sent to Swissmedic 25.06.2021)
  (labelling CH-REP, registration, PRRC, parallel import)
- Ordonnances based on hope for MRA → unusable in third country reality
  → IvDO in consultation rejected by SMT
  → Request re. amendment of MedDO (sent to BAG 05.07.2021)

Problem: Import of MD to CH

Market attractivity (market size, price level)

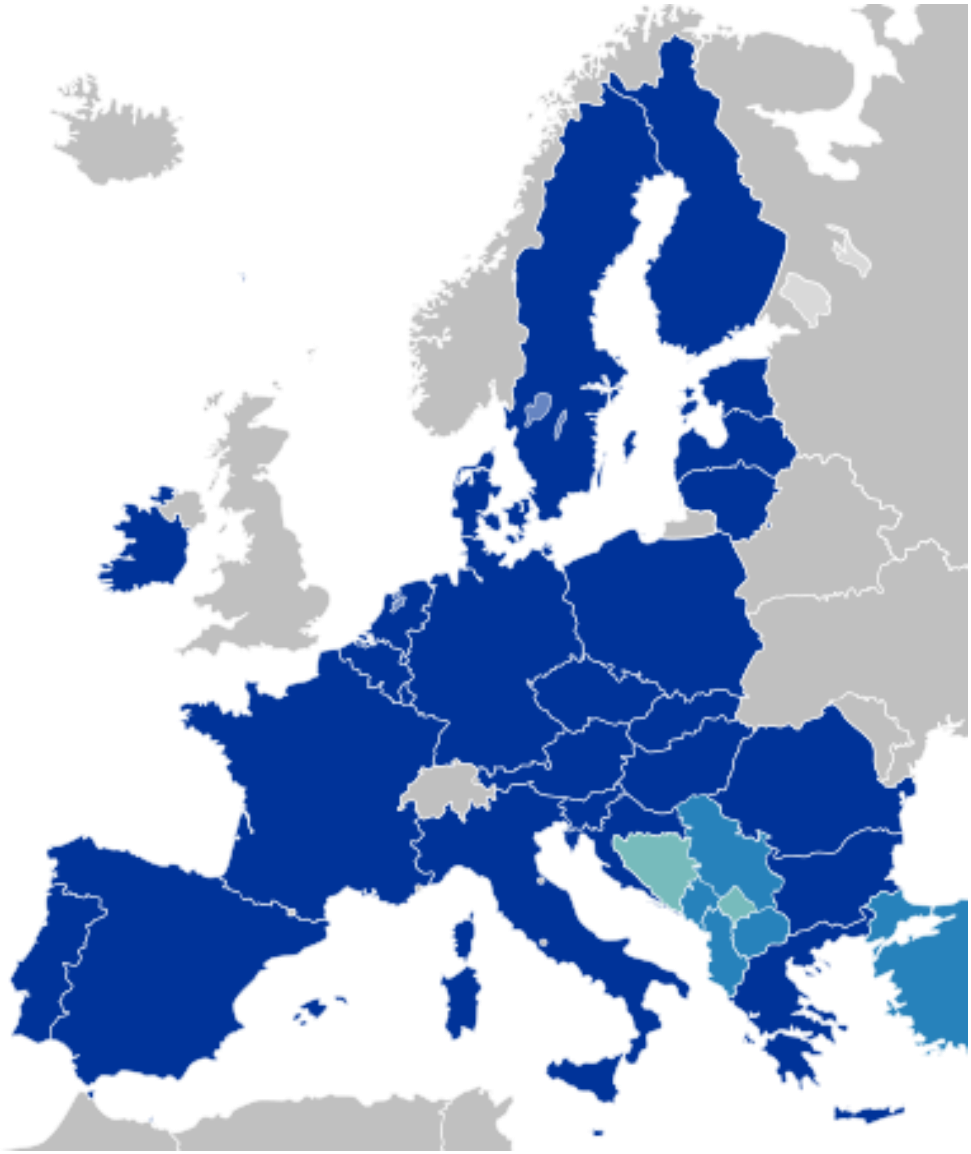
- EU: 446 Mio. inhabitants (without UK & CH)
- UK: 66 Mio. inhabitants (15% of EU)
- CH: 8 Mio. inhabitants (2% of EU)

Business decision of foreign manufacturer to place product on markets or not.

Goal A: Regulatory environment remains attractive for Swiss medtech companies

Goal B: The supply of Swiss patients with medical devices remains at the current level

→ Regulatory environment remains attractive for foreign medtech companies (from EU and RoW)



How many Swiss AR are needed?

Approx. 5'000 foreign manufacturers (300’000 medical devices)

→ In best case: 5’000 Swiss AR
→ Divided among 100 importers/distributors and 20 consultant companies:
>40 mandates per company

Hurdles:
Contract negotiation for written mandate, joint liability, access to TD, responsibilities
→ Needs sufficient number of Swiss AR and sufficiently long transition period

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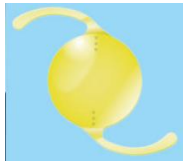
Which MD will be missing?

- Up to 25% of all importied MD (12% of all MD in use today)
- Which ones? Cannot be predicted today!

Depends on:
- Regulatory requirements (MRA, TP for Swiss AR)
- Willingness of Swiss companies (Swiss AR)
- Willingness of foreign companies (business case)
- Willingness to pay higher remuneration (Swiss patients)

→ **Will become clearer only in 2022 (after TP)**
(List of missing products to be established by SMT)



Effect of Third Country Status for CH

Swiss Manufacturers

- **Export** of MD to EU only with EAR (EU Authorised Representative)
- Set-up costs CHF 110 Mio., recurring costs CHF 75 Mio./year
- **Loss of attractiveness** of Switzerland as location for the medtech industry (Start-ups, SME, Multi.nationals)
- Recommendation for action «As well as» by Swiss Medtech, April 2019

Swiss Importers & Distributors

- **Import** of MD into CH only with Swiss AR (Swiss Authorised Representative)
- Set-up costs CHF >50 Mio., recurring costs CHF >30 Mio./year
- **Supply gap for Swiss patients**, as many foreign manufacturers not willing to install Swiss AR
- Recommendation for action «Plan now» by Swiss Medtech, Dec. 2020

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Without MRA

With MRA

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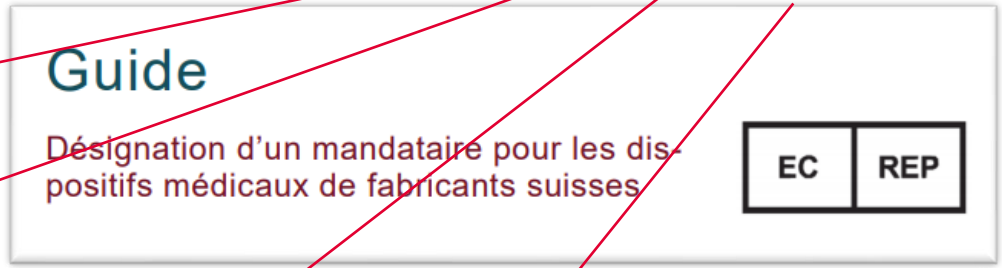
Support by Swiss Medtech

NEW

1. Information for Swiss manufacturers
   - Guidance for CH manufacturers re. EAR
   - Webinars and Q&A sessions
   - Special webinar for SQS-certificate holders



2. Information for Swiss importers & distributors
   - Guidance for CH distributors and importers re. Swiss rep.
   - 1-pager as information for foreign suppliers
   - Model contract for the appointment of a CH authorised representative
   - Webinars and Q&A sessions

https://www.swiss-medtech.ch/news/mdr-portal

Take Home Message

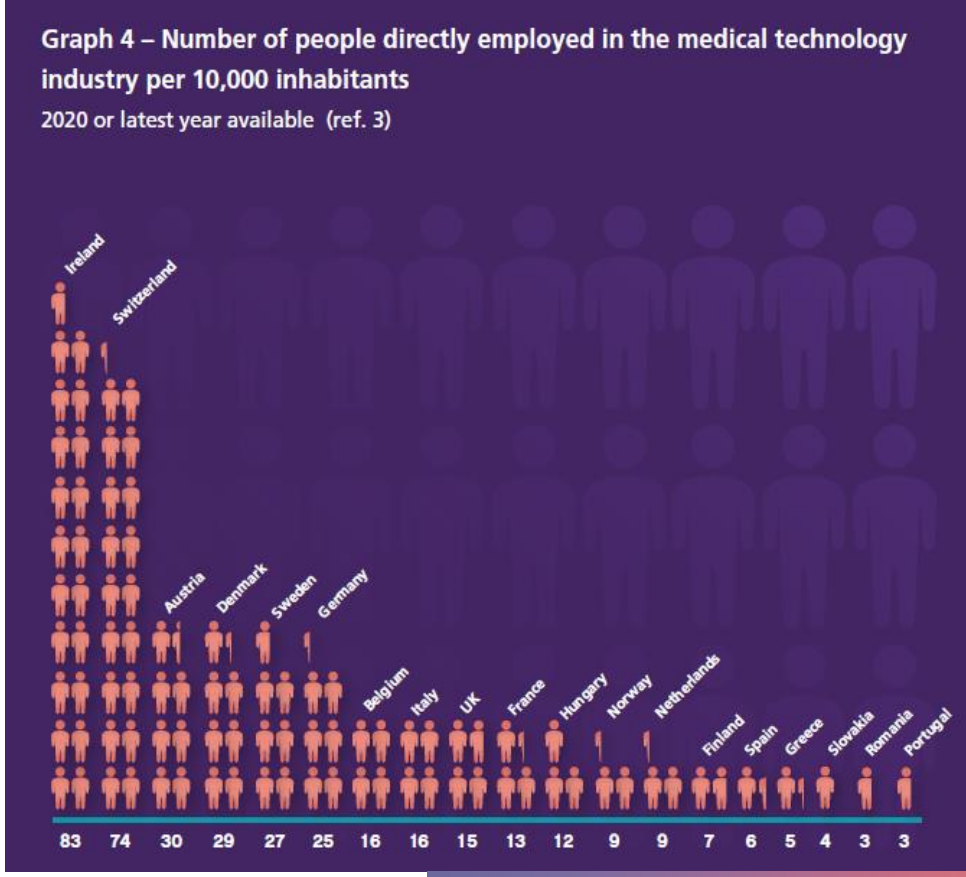
Vision Swiss Medtech

- Switzerland is the world's most attractive location for the development and production of complex, innovative medical devices.

Reality for Swiss Medtech industry

- Problems for the export of Swiss medical devices to the EU
- Problems for the import of medical devices into Switzerland
- Gradual but permanent loss of attractiveness

→ Medtech companies have to meet third-country requirements, making them independent of political decisions!



The European Medical Technology Industry in Figures 2021

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Is Switzerland still part of Europe?

Yes, geographically

Yes, ideologically

No for medtech business