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Die Schweiz als Drittstaat: Was gilt für Medizinprodukte mit einem SQS-Zertifikat?

6. Juli 2021

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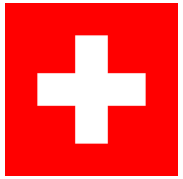
Die Schweiz und MDR

- MDR regelt Inverkehrbringung von Produkten im EU-Binnenmarkt
  → EU-Marktzutritt für Firmen weltweit

- MepV = Medizinprodukteverordnung (äquivalent zu MDR)
  → CH-Marktzutritt für Firmen weltweit



- MRA = Mutual Recognition Agreement
  Vertrag über den Abbau technischer Handelshemmnisse CH-EU
  → Privilegierter EU-Marktzutritt für CH-Firmen

- InstA = Institutionelles Rahmenabkommen
  Regelt automatische Übernahme der EU-Rechtsbeschlüsse für CH

Situation der Schweizer Medtech Industrie

→ Kein InstA

→ Keine Aktualisierung des MRA

Interview mit Bundespräsident Parmelin am 26.05.2021

→ Schweiz ist seit 26.05.2021 Drittstaat für die EU

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Ohne MRA

Mit MRA

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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 validity of SQS certificates!
→ No access to EUDAMED for Swissmedic!
→ **No regulatory certainty!**

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.

Reaktionen der EU-Mitgliedstaaten

- Spanien:
  CH-Produkte brauchen EAR und EU-NB
  Importeure benötigen Importlizenz von AEMPS
  Übergangsfrist bis 30.09.2021

MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Información sobre productos sanitarios en base al acuerdo de reconocimiento mutuo (MRA) UE- Suiza

Fecha de publicación: 10 de junio de 2021

- Italien:
  Ankündigung, CH-Produkte mit SQS-Zertifikat nicht mehr zuzulassen

- Deutschland:
  Ankündigung in 4 Bundesländern durch Ministerien (Freiburg, Köln, München, Düsseldorf), CH-Produkte mit SQS-Zertifikat nicht mehr zuzulassen

Legale Abklärung durch Medtech-Europe

SIDLEY

PRIVILEGED AND CONFIDENTIAL

MEMORANDUM – 2 JULY 2021

EU/EEA MARKET ACCESS FOR "SWISS LEGACY DEVICES" POST ABANDONMENT OF SWISS-EU MRA

MedTech Europe asked us to assess how the abandonment of EU-Swiss negotiations on updating the chapter on medical devices in the EU/Swiss Mutual Recognition Agreement[3] ("**MRA**") and the "**Notice to Stakeholders**" published by the European Commission ("**Commission**") on 26 May 2021[4] impact manufacturers that are based in Switzerland.

Legale Abklärung durch Medtech-Europe

Key Conclusions of the Memorandum:

- There is no legal basis for the requirement of a new AR to benefit from Article 120 transitional provisions.
- There is no legal basis for the requirement of changes to labels of devices benefitting from article 120 transitional provisions.
- There is no legal basis for declaring that certificates issued by Swiss notified bodies are no longer valid.

2

MedTech Europe
from diagnosis to cure

Legale Abklärung durch Medtech-Europe

The EU and its Member States must continue to permit EU sales of all MDD devices with a valid certificate issued by a Swiss conformity assessment body prior to 26 May 2021 and may not require an EU CE certificate as a condition for importation, as well as MDR-compliant devices put on the market in Switzerland;

Legale Abklärung durch Medtech-Europe

We understand that the Commission has not informed the Joint Committee of a wish to have the MRA revised. The Commission has not consulted the Joint Committee with a view to suspending application of any part of Annex 1. The Commission has not submitted a notice of denunciation to the Switzerland. Therefore the MRA and its entire Annex 1 apply in full unless and until the procedures for revision, suspension or denunciation have been completed, with due observe of acquired rights.

Similarly, the Swiss conformity assessment body SQS, which has been included on the list of recognised conformity assessment bodies under Chapter 4 of Annex 1 of the MRA[28], has issued at least 85 product certificates under the MDD, for types of medical devices manufactured by 8 EU-based and 54 Swiss-based manufacturers, and covering at least 10 types of products put on the market by EU manufacturers, and 75 products of Swiss manufacturers. We understand that SQS achieved its national accreditation under the MDR on 28 January 2021,[29] but that SQS has not yet been added to the MRA list of recognised conformity assessment bodies that can carry out MDR assessments. Under the MRA-conform interpretation, all of the devices put on the market in the EU under these registrations and certificates have been treated as devices properly bearing a CE mark issued by a properly-accredited notified body meeting the requirements of EU law.

Legale Abklärung durch Medtech-Europe

It is inconsistent with the MRA for a Party to block a decision in the Joint Committee on the basis of extraneous political considerations, such as those that explicitly motivate the Notice to Stakeholders. In effect, the Commission is misusing it position in the Joint Committee to penalize Switzerland for the position that it has taken in bilateral negotiations that have nothing to do with the MRA. This is inconsistent with the EU's duty to implement the MRA in good faith, to ensure the "smooth functioning" of the MRA. The application of the MRA, which was agreed in 2002, is not conditioned on the conclusion of an institutional framework agreement between the two Parties. Thus, the Commission's position deliberately undermines and obstructs the MRA by misuse of powers ("*detournement de pouvoir*").

It is surprising that an institution representing the EU, which is founded on the rule of law,[16] and expounds that fundamental value with some regularity, would take the position that the EU can unilaterally decide to cease applying a valid international treaty by issuing a press release with a notice to stakeholders that has no formal legal basis or status.

Was tun als Hersteller mit SQS-Zertifikat?

To Do:

- EU-Bevollmächtigter (EAR) und Importeur benennen
- Suche nach EU-NB
- Systemzertifikat unter MDR
- Zertifizierung aller Produkte unter MDR
- Weil nicht konform mit MDR-Anforderungen:
  - Plan zur Erreichung der Konformität erstellen
  - Vorlage des Plans bei Behörde des Mitgliedstaates des EAR (Ausnahmeregelung unter Art. 97 MDR)

Artikel 97

Sonstige Nichtkonformität

(1) Stellen die zuständigen Behörden eines Mitgliedstaats nach Durchführung einer Bewertung gemäß Artikel 94 fest, dass ein Produkt nicht die in dieser Verordnung niedergelegten Anforderungen erfüllt, aber kein unvertretbares Risiko für die Gesundheit oder Sicherheit der Patienten, Anwender oder anderer Personen oder in Bezug auf andere Aspekte des Schutzes der öffentlichen Gesundheit darstellt, so fordern sie den entsprechenden Wirtschaftsakteur auf, der betreffenden Nichtkonformität innerhalb eines der Nichtkonformität angemessenen, eindeutig festgelegten und dem Wirtschaftsakteur mitgeteilten Zeitraums ein Ende zu setzen.

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Unterstützung durch Swiss Medtech

NEU

1. Information an die Schweizer Hersteller (Export)
   - Wegleitung für CH-Hersteller zur Benennung eines EU-Bevollmächtigten
   - Webinare und Q&A-Sessions
   - Spezial-Webinar für Firmen mit SQS-Zertifikaten

2. Information an die Schweizer Importeure & Händler
   - Wegleitung für CH-Händler und Importeure zur Benennung eines CH-Bevollmächtigten
   - 1-Pager als Information für die ausländischen Lieferanten
   - Mustervertrag für die Benennung eines CH-Bevollmächtigten
   - Webinare und Q&A-Sessions

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

Übersicht: Probleme als Drittstaat

Export:

- 54 CH-Hersteller und 8 EU-Hersteller «ohne gültige Zertifikate» (SQS) → brauchen EAR, EU-NB, Systemzertifikat, Produkt-Zertifikate unter MDR
- 300 CH-Hersteller mit gültigen Zertifikaten (EU-NB) → brauchen EAR ohne Übergangsfrist

Import:

- 5000 ausländische Hersteller brauchen CH-REP mit kurzer Übergangsfrist (7/10/14 Monate minus Zeit bis Klärung) → Gefahr für Versorgungssicherheit für CH-Patienten in 2022
- Swissmedic verliert Zugang zu EUDAMED → Gefahr für Produktesicherheit

MepV & IvDV:

- Neue MepV generiert Unklarheiten → über 500 Anfragen bei SMT, über 1000 bei Swissmedic → braucht dringend Klärung der offenen Fragen (Labelling CH-REP, Registrierung, PRRC, Importeure)
- Verfasst mit Hoffnung auf MRA → In Drittstaat-Realität nicht anwendbar

Vision vs. Realität

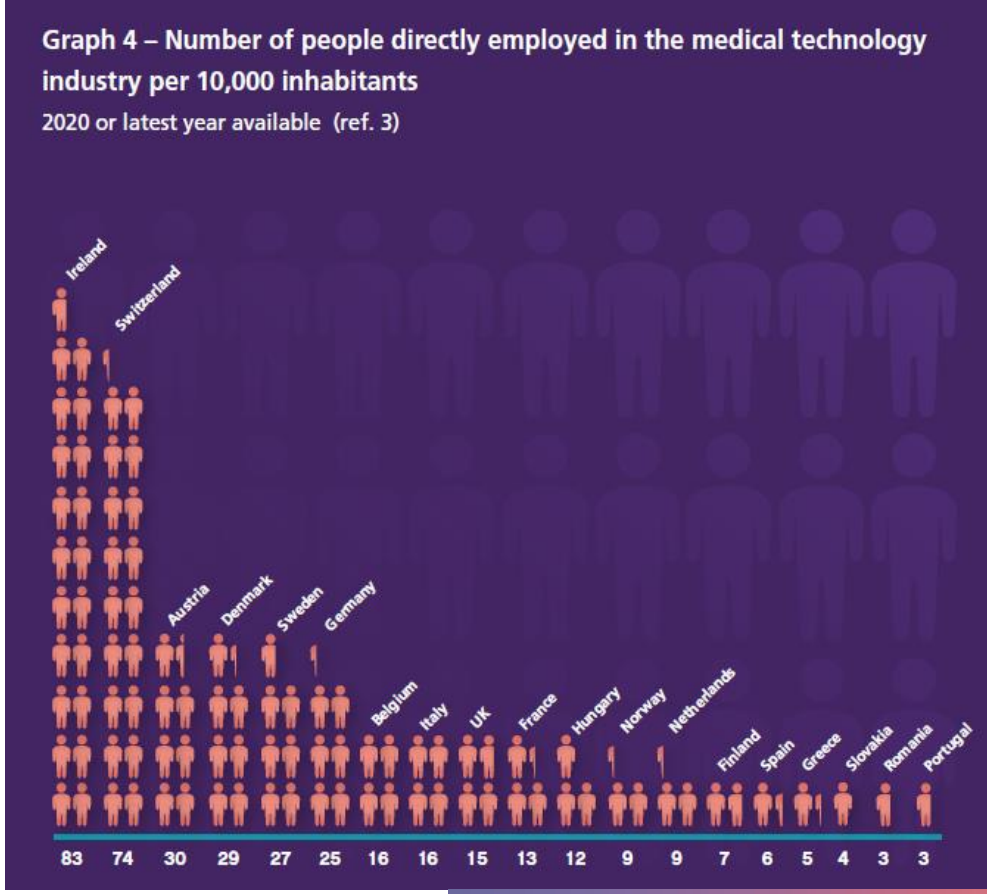
Vision Swiss Medtech

- Die Schweiz ist der weltweit attraktivste Standort für die Entwicklung und Fertigung von komplexen, innovativen Medizinprodukten.

Realität für Schweizer Medtech-Industrie

- Probleme für Export von Schweizer Medizinprodukten in die EU
- Probleme für Import von Medizinprodukten in die Schweiz
- Attraktivitätsverlust schleichend aber nachhaltig

→ Medtech-Firmen müssen Drittstaat-Anforderungen erfüllen, damit sie unabhängig von politischen Entscheiden werden!



The European Medical Technology Industry in figures 2021

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Ohne MRA

Mit MRA