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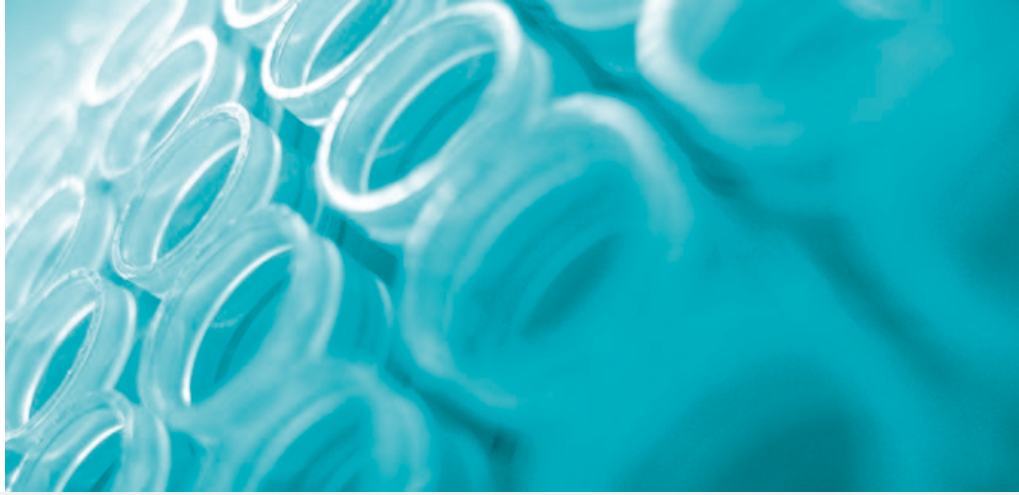


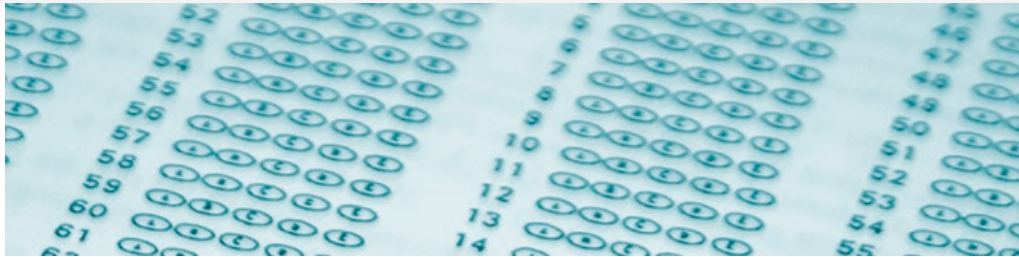
Presented by: ISS AG

Practical differences in the regulation between Switzerland - EU

Swiss Regulatory Landscape in the Making

Bernhard Bichsel, 11 March 2024, Online

Version 1



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Regulatory Trends

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Regulatory Trends

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– Regulatory Requirements are **increasing worldwide**

– **Efforts to regulate new technologies** (e.g. AI) by the authorities

– **Stakeholders** are more and more in responsibility to **ensure compliance** throughout the **entire lifecycle** of a medical devices

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Regulatory Trends

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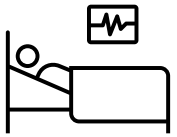
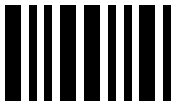
Regulatory Requirements



Clinical Performance

Post-market surveillance



UDI and device traceability

Databases and transparency

Role of economic operators

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Regulatory Framework EU - CH

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Legal Framework

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Responsible Body	European Commission	FOPH
Legal Framework	MDR IVDR	TPA
Implementation/Execution	(national laws) Guidance Documents	MedDO IvDO
Approach	Decentralised	
Notified Body	Required	
Representative for foreign manufacturers	Required	
Classification	I – I(s) – I(m) – I(r) – IIa – IIb – III	
Licence validity	Class I: unlimited, Rest: max 5 years	

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Two perspectives

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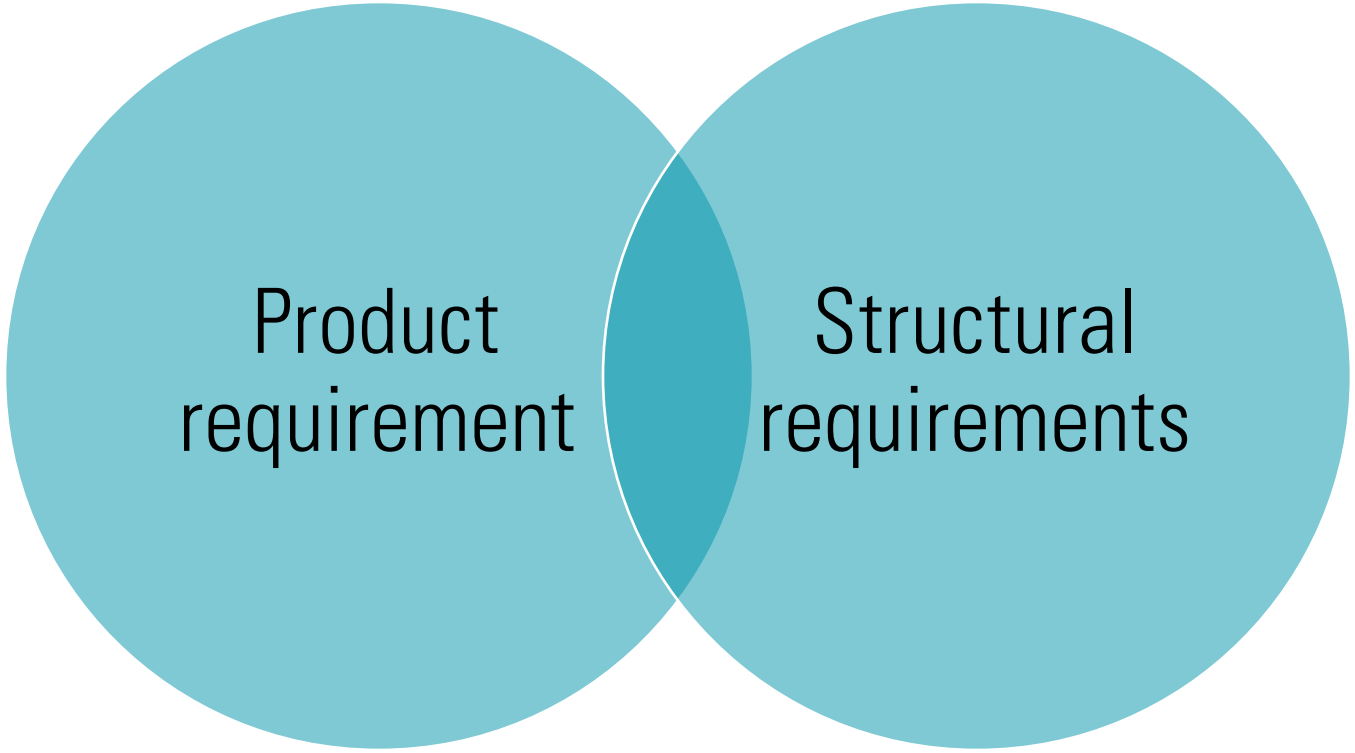

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Product requirements - similarities

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Product requirements EU & CH

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- EU and Switzerland: **Essential safety and performance requirements** according to Annex I EU MDR

- This means that Switzerland has basically **the same product requirements** as the EU

- The CE certificate is recognised as proof of conformity

- **Differences** can be found **primarily** in the requirements for **economic operators**

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Structural requirements - differences

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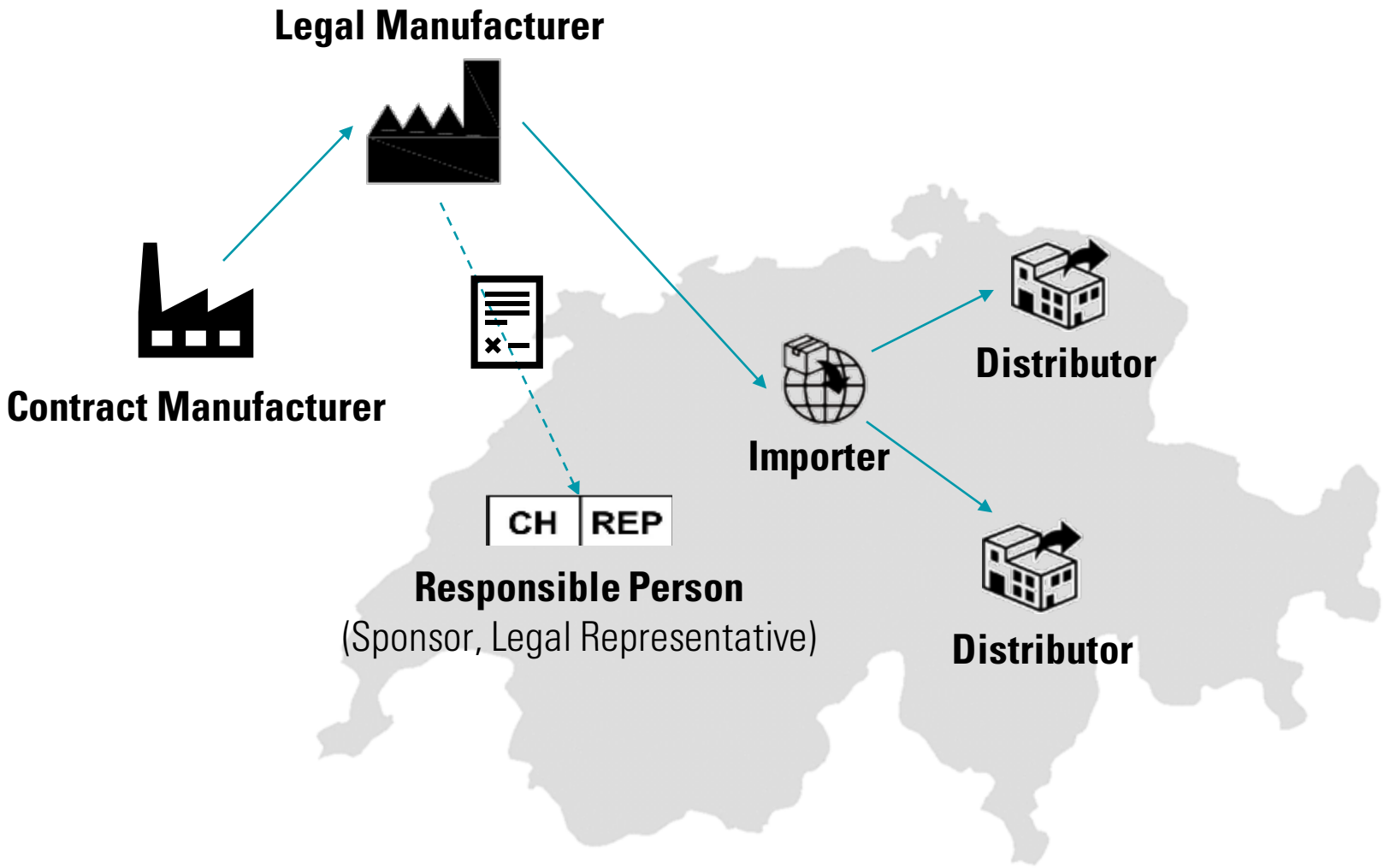
Economic Operators



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Overview about differences

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National CH regulations: Examples

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- **In General Points**
  - Terminology (e.g. benannte Stelle vs. bezeichnete Stelle)
  - Special Cases e.g. reuse of single-use devices
  - …
- **Market access**
  - Registration: Economic Operator, CH-Rep, …
  - Notification of medical devices, IVDs, devitalised human tissue
  - Three official languages
  - …
- **Market Surveillance**
  - Our observation: Different interpretation of enforcement in the market on product level (e.g. qualification and classification of software)
  - …

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Current Discussions

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Non-European Authorized Products

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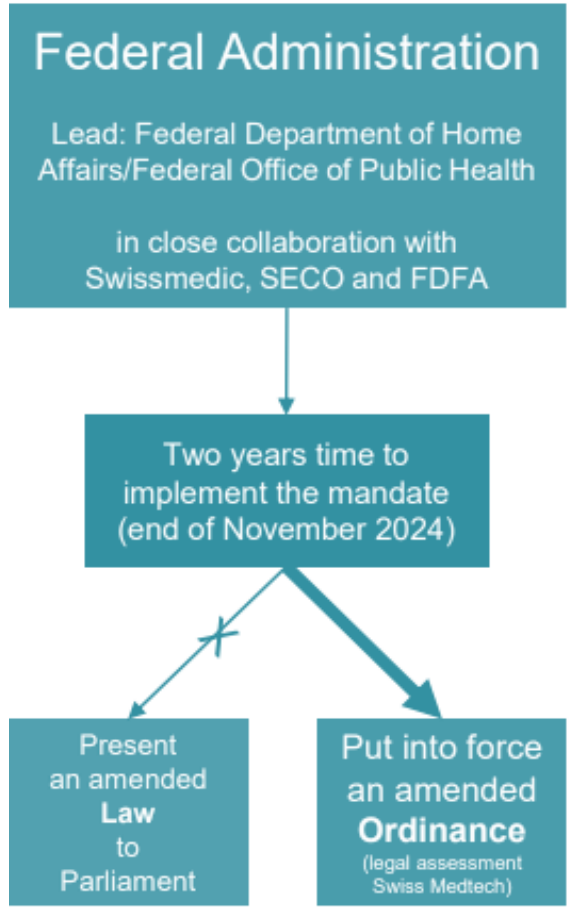
– The Swiss Parliament instructed the Swiss government (Federal Council) based on motion 20.3211 to **adapt the national legal basis** so that medical devices of **non-European regulations** may also be used in Switzerland

– Main focus: FDA authorized products



Source: Swiss MedTech

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Conclusion

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Conclusion

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- **In principle**, the **product requirements** for medical devices in Switzerland **differ little** from those in the EU

- There are **primary structural differences**, such as economic operators, reporting obligations or labelling requirements

- Due to the lack of involvement of the Swiss authorities, we are increasingly observing **differences in enforcement in the market on product level** (e.g. qualification and classification of software)