SWISS MEDTECH

Destination Switzerland? The Impact of Swiss Parliament's Recent Decision Concerning Medical Devices with FDA Authorization

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Switzerland

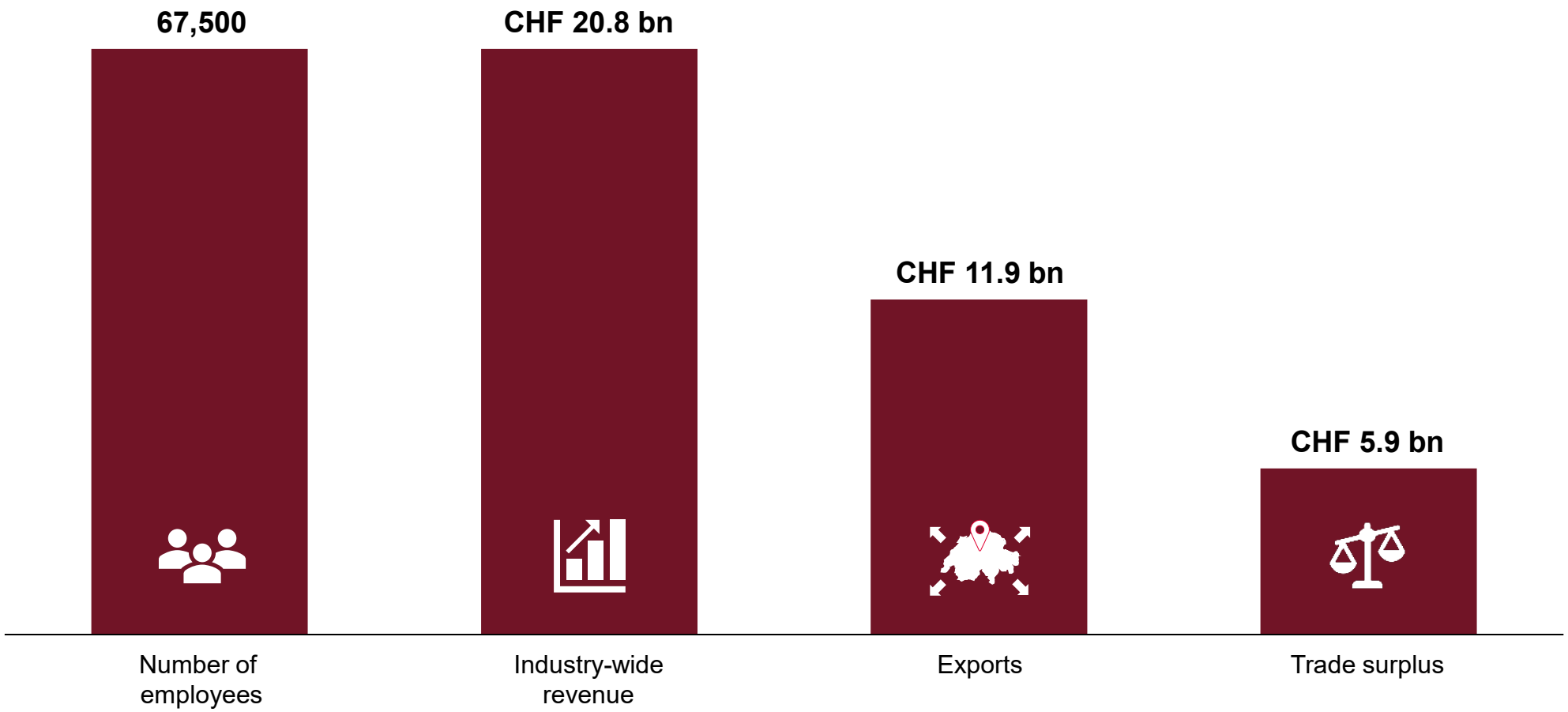
- Profile of the country at the heart of Europe
- Medical technology sector
- Supply of medical devices
- Excursus: Swiss-European Union (EU) relationship

Profile of Switzerland

- 15,946 square miles (US)
- Population 8.9 million (January 2023)
- GDP 800.6 billion USD (2021)
- «High-tech» location
- Leading universities, technical institutes, research institutions
- Most innovative country in the world (Global Innovation Index 2022)
- Economically important medtech industry

Swiss medical technology industry

Key figures 2021

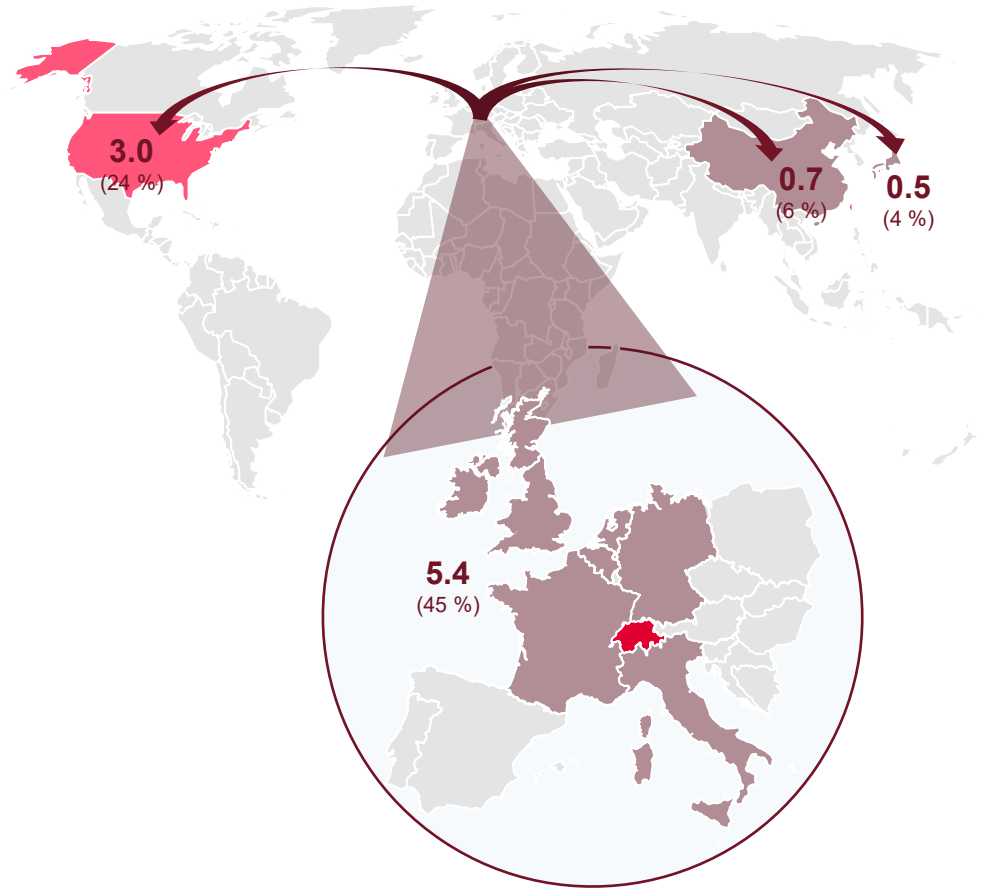


Source: SMTI 2022

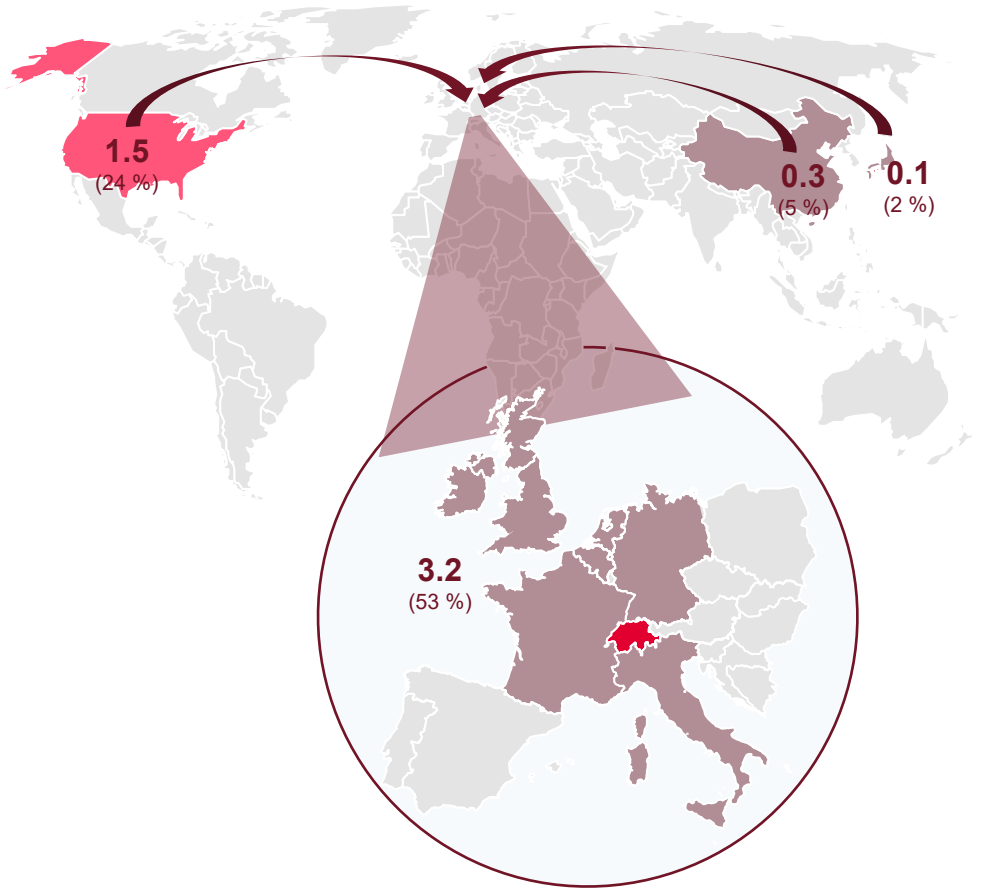
Exports & Imports 2021

in billion CHF

Total exports: CHF 11.9 billion

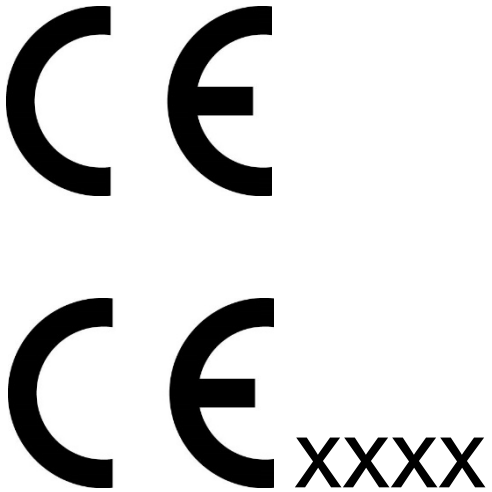


Total imports: CHF 6.0 billion



Supply of medical devices

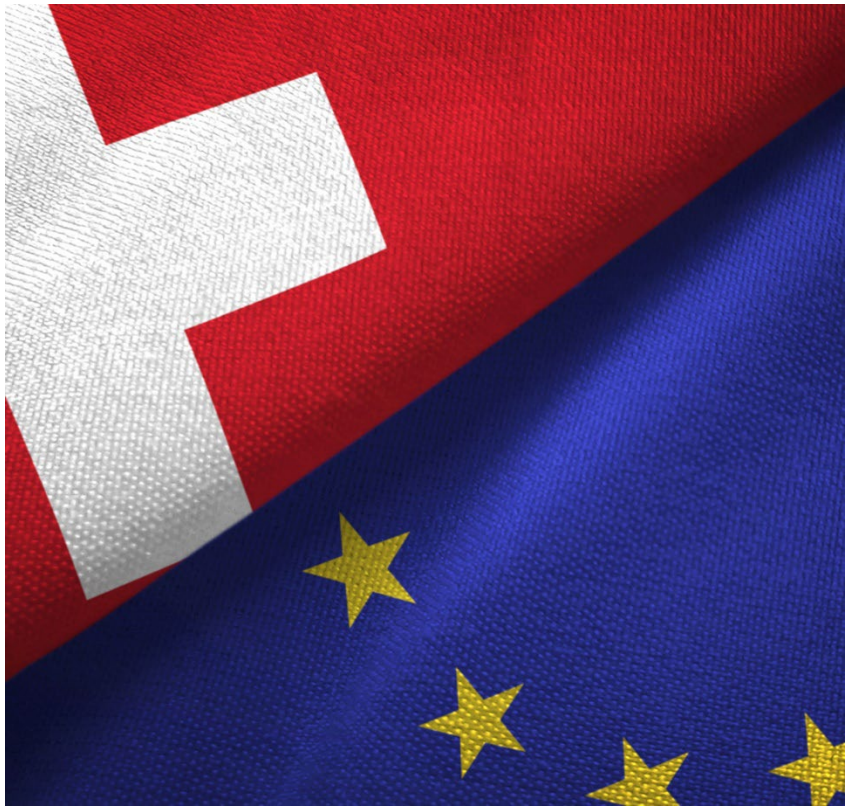
Current situation in Switzerland



- **Dependent on imports**
  Switzerland – like many other countries – is not able to independently produce the full range of medical products it requires.

- **CE marking required**
  In Switzerland, only medical devices that comply with the European Medical Device Regulation (MDR) may be used. This requirement applies to medical devices originating from round the globe.

Excursus: Swiss-EU relationship



- Switzerland is not a member of the European Union (EU)
- Set of bilateral agreements
- Switzerland unilaterally breaks off negotiations on an institutional framework agreement in May 2021
- EU subsequently declares bilateral Mutual Recognition Agreement (MRA) no longer applicable
- Since then, obstacles restrict mutual trade in medical devices

Switzerland’s approach regarding FDA medical devices

- The decision by the Swiss Parliament of 28 November 2022
- Background of Motion 20.3211
- Implementation of Motion 20.3211
- Crucial success factors for the implementation of Motion 20.3211

The decision by the Swiss Parliament of 28 November 2022

Content

The Swiss Parliament instructed the Swiss government (Federal Council) based on motion 20.3211 to adapt the national legal basis so that in future – in addition to medical devices complying with European Medical Device Regulation (MDR, CE-marking) – medical devices of non-European regulations may also be used in Switzerland to supply the Swiss population.

Motion 20.3211 submitted by Damian Müller, member of the Council of States

«For more room for manoeuvre in the procurement of medical devices to supply the Swiss population»

Supply of medical devices

Situation in Switzerland in the future

CE

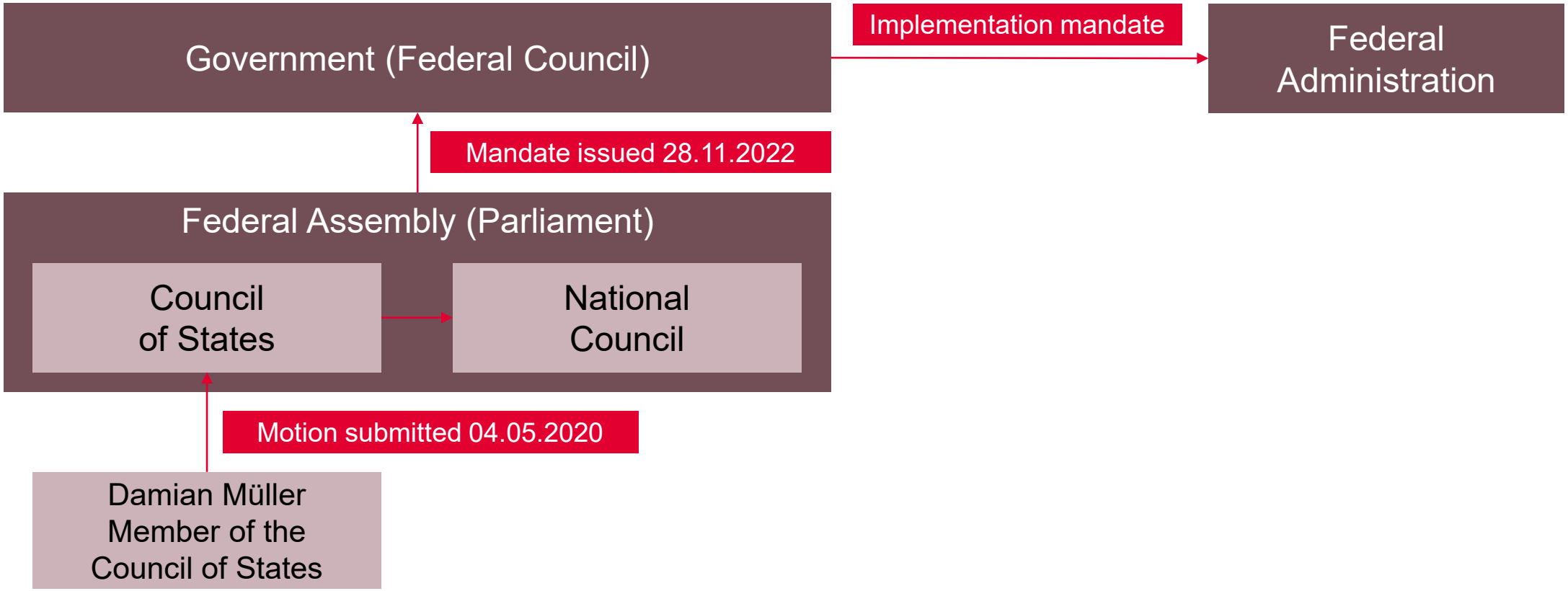
CE xxxx + FDA AUTHORIZED + ...

Pioneering decision

- Medical devices with FDA authorization are not permitted in the EU.
- Switzerland plays a pioneering role in Europe.
- The United Kingdom (UK) – no longer a member of the EU since the beginning of 2020 – is reportedly working on a similar regulation.

The political process in Switzerland

How the mandate based on Motion 20.3211 came to pass



Essential to note

- **Not yet a reality:** FDA products are still not permitted in Switzerland
- **Mandate issued – implementation to follow:** National law must be adapted first. Only then may FDA products be imported into Switzerland.
- **Parallel recognition:** The mandate doesn't aim to abandon CE-marked medical devices, but rather allow for parallel recognition of medical devices from non-European regulatory systems.
- **No onward export – no gateway to the EU:** Once the revision of the legal basis being in force FDA products may be imported into Switzerland only to ensure its own supply. Subsequent exports from Switzerland to the EU will not be possible.

Why are FDA products important for Switzerland?

1

To guarantee the sufficient supply of medical devices to the Swiss population.

2

To ensure that the Swiss population has access to the newest medical products.

3

To strengthen the innovative power and competitiveness of the Swiss medical technology industry.

MDR makes medical devices disappear from the market in Europe

1

- Over **15%** of existing medical devices in **Europe** will disappear because transition from the old (MDD) to the new EU regulation (MDR) is not profitable. This **streamlining of portfolios** is already ongoing.
- **Niche products** – even established ones – often do not generate sufficient **clinical data** for transfer to the MDR. These products will be unavailable in **Europe**.
- Moreover, **specifically for Switzerland**: an additional **15%** of medical products imported to date are already missing – because the import hurdles are too high.

Access to innovative products is not ensured

2

- **50%** of companies surveyed across Europe prioritise the **FDA for the initial approval** of their medical devices. The trend is on the rise.
- These medical products do not come to Europe or Switzerland at all, or at best with a **delay of years**.
- The reasons given are, on the one hand, the challenges in connection with MDR and, on the other hand, the **FDA's progressiveness** regarding **digitalization.**

MDR weakens innovative power

3

- MDR creates a backlog of innovation – tying up resources otherwise needed for innovation.
- Therefore, also less research & development.
- FDA is keeping pace with digitalization.
- For digital technologies such as «artificial intelligence» progressive regulation is crucial.
- Diversification of regulatory systems important for medtech companies.

➢ If we lose more and more research and development, then we will also lose many bright minds as well as production and value creation in Switzerland.

Crucial success factors

for the implementation of motion 20.3211

- **Urgent:** Implementation must be initiated quickly in view of the effects of the MDR on patient care and on Switzerland as location of innovation.
- **Comprehensive:** In principle, all medical devices with FDA authorization should be recognized – both existing and new medical devices.
- **Modular:** Implementation should be future-oriented and should include the option to recognise medical devices from other regulatory systems (in addition to medical devices with FDA authorization) in the future.
- **Practicable & workable:** The parties concerned (industry, health care institutions, etc.) must be able to rely on a clear and understandable legal basis.

Do you have questions?

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