

# Medical Device Shortage Reporting Organization

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#### Founders and Operators

#### Dr. Andrea Schütz

- Head of the Health & Medical Law
  Team of Prager Dreifuss AG
- 15 years of experience in the health and administative law sector
- Former investigator in the criminal division of Swissmedic
- Provides legal expertise for the MDSRO



Dr. Andrea Schütz





#### **Angelina Hakim (MSc.)**

- Founder and CEO of QUNIQUE
  GmbH Switzerland and Germany
- 15 years experience in the medical device field
- Lead Auditor for MDSAP & ISO 13485:2016, PRRC, Trainer (MDR, IVDR etc.)
- Provides Regulatory Affairs and Quality Management System
   Expertise for the MDSRO



## History



Presentation at the Swiss Medtech MDR/IVDR conference on October 29, 2022

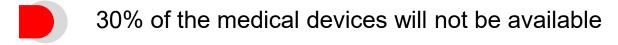
Media release in November 2022

Website since January 31st, 2023



### **Importance**





- 10% of the imported medical devices are missing already
- The Federal Council sees no need for action and refers to the exceptional authorisation
- This exceptional authorisation requires proof that medical devices are missing and cannot be replaced
- MDSRO makes supply shortages in Switzerland measurable and visible for the first time
- MDSRO can provide the evidence required for the exceptional authorisation



### Objectives

To make shortages measurable and visible

To provide legal and technical support to economic operators in the event of shortages



To increase political pressure



#### Benefits



Voluntariness and anonymity: no state reporting office with reporting obligations, compulsory stockpiling and other mandatory measures

Awareness of the problem: no government feasibility studies and cost-benefit analyses were necessary

Private initiative: no legislative adjustments were required

Independence: all healthcare stakeholders benefit

No judgement of importance : no triage into important and allegedly non-important medical devices

Active support: Not only a static monitoring and reporting office



# **Your Notification** regarding missing **Medical Devices** In Switzerland



#### Ihre Meldung betreffend fehlende Medizinprodukte in der Schweiz



- schwerwiegende Auswirkungen
- keine Auswirkungen



- Angelina Hakim und Andrea Schütz werden Sie kontaktier





#### Solutions



Exceptional authorisation according to MedDO and IvDO (Ausnahmebewilligung)

**Technical and legal support** 

Obtaining a general ruling (Allgemeinverfügung)

Etc.



### Thank you for your attention!



