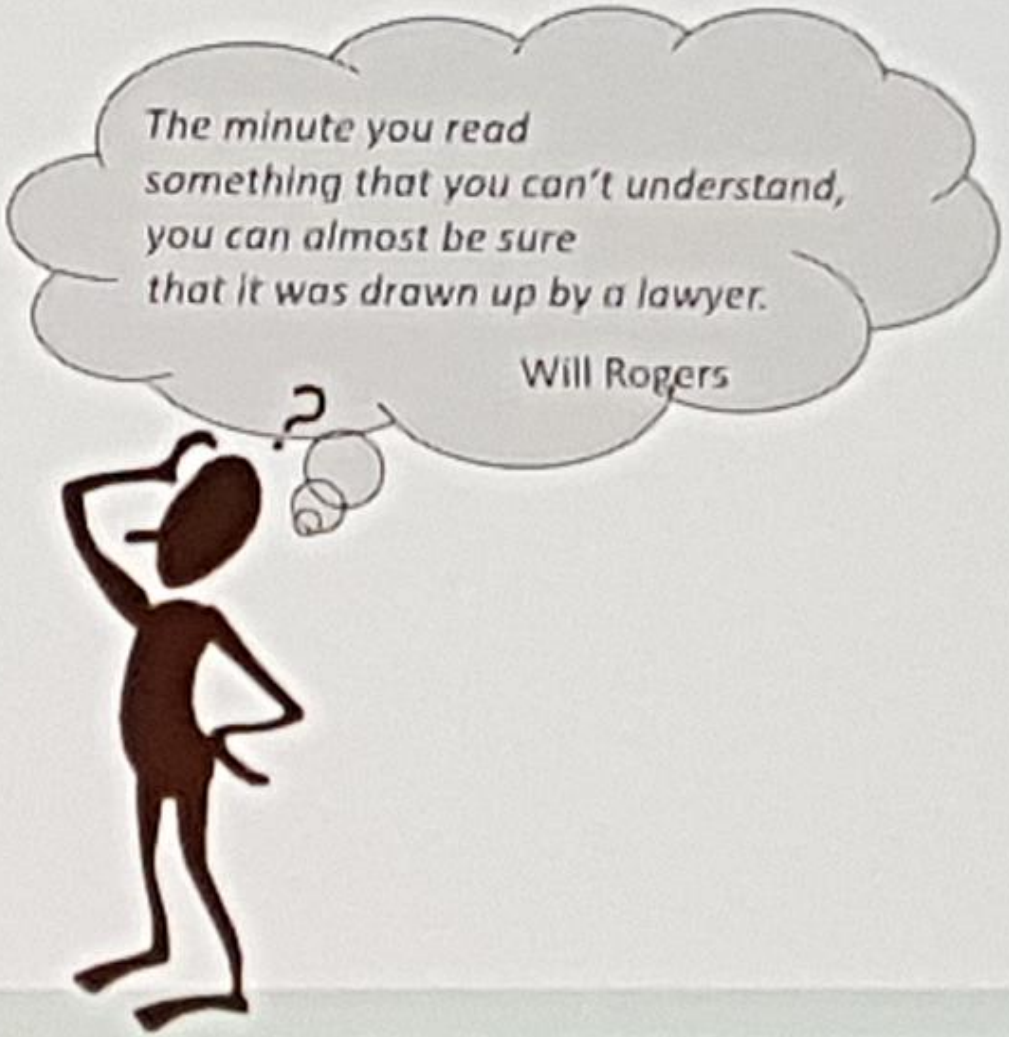
Legal framework: Impact of EU Medical Devices Regulation on Reprocessing of Single Use Devices in Europe and Germany

- **Single Use Medical Devices = Single Use Devices = Single-use devices = (in the following referred to as) SUD**

Note: the opposite = Multiple Use Devices (MUD)

- **Definitions: Regulation (EU) 2017/745 = Medical Devices Regulation = (in the following referred to as) MDR**
- **Art. 2(8) MDR: single-use device means a device that is intended to be used on one individual during a single procedure**

Regulation (EU) 2017/745 about Medical Devices



AGENDA

- Current state of SUD reprocessing - Germany
- Current state of SUD reprocessing - EU
- History and procedure of legislation of the MDR
- Reprocessing of SUD according to MDR provisions
- Outlook

DE

Germany

CURRENT STATE OF SUD REPROCESSING

- Legal situation according to the German Medical Devices Law
- No legal ban of SUD reprocessing
- Reprocessing is regulated by the Decree about the Operating of Medical Devices – the same provisions for SUD and MUD
- Provisions about the duly reprocessing quality, taking into account the reprocessing information supplied by the manufacturer, using suitable validated procedures
- Compliance with RKI/BfArM Guideline “Hygiene Requirements for the Reprocessing of Medical Devices”
- RKI = Robert Koch Institute, BfArM = German Higher Authority

DE

EU/EEA: patchwork

- clearly permitted (DE) DE
- permitted acting as a manufacturer (UK) GB
- not prohibited/ not regulated by law (most of the states)
- clearly prohibited (FR) FR

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Outside of EU/EEA

- US permitted (manufacturer, list of reusable SUD, 3 levels) US
- CND permitted (manufacturer, licence necessary for commercial SUD reprocessors) CA
- JP neither permitted nor banned; performed JP
- CH considered a manufacturer of a new product CH
- Third-world countries not regulated but performed (Popp et al., Int. J. Hyg. Environ. Health 2010, 302)

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FACTSHEET: History and procedure of legislation

REGULATION (EU) 2017/745 ABOUT MEDICAL DEVICES

- Discussion about reprocessing of SUD
- Art. 12a of the Directive 2007/47/EC: European Commission (EC) has to draft a report about reprocessing of SUD
- 2010 opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
- 2010 reprocessing report of the EC
- 2012 EC Draft of MDR including provision about SUD reprocessing: e.g. reprocessor = manufacturer, list of SUD classified as reprocessing permitted (positive list)

cancelled

- 2014 opinion of the European Parliament (EP) with 347 amendments: e.g. reprocessor = manufacturer, list of SUD classified as reprocessing forbidden (negative list)
- 2015 opinion of the European Counsel: e.g. reprocessor = manufacturer; different requirements for SUD reprocessed and used within a **health care institution**; SUD may also be reprocessed by an **external reprocessor** at the request of a health care institution, provided that the reprocessed SUD in its entirety is returned to that health care institution (legal requirements of the current law see next charts)

Reprocessing of SUD according to MDR provisions at a glance – Art. 17 MDR

REGULATION (EU) 2017/745 ABOUT MEDICAL DEVICES

- **Option #1: reprocessing of SUD according to Art. 17(2) MDR = provisions for manufacturers apply**
- **Option #2: derogation from Art. 17(2) – Art. 17(3) and (4) MDR SUD reprocessed and used within a health care institution or – as a service provider – reprocessed on behalf of such a health care institution**
  - Specific requirements; Common Specifications for the SUD reprocessing
  - Certification by Notified Body
- **Option #3: total ban or restrictions of SUD reprocessing at a national level**

Requirements concerning SUD reprocessing (1)

- only SUD marketed acc. to MDR or acc. to Directive 93/42/EC
- reprocessing = safe according to the latest scientific evidence
- safety and performance equivalent to that of the original device
- requirements laid down in Art. 5(5) sub-paragraph (a), (b), (d), (e), (f), (g) and (h) are met (provision regarding manufacturing and using within a health care institution)
- performed in accordance with CS containing details about risk management, validation of the entire process, product release and performance testing, QM system, reporting of incidents, traceability

Requirements concerning SUD reprocessing (2)

- option at a national level: information to patients about the use of reprocessed devices within the health care institution
- labelling: reprocessor, information acc. to Annex I Sect. 23, no manufacturer of the original SUD
- instructions for use: reprocessor, information acc. to Annex I
  Sect. 23, manufacturer of the original SUD (optional)
- EC will make publicly available information about national provisions acc. to Art. 17(3) and (4) MDR as well as information about bans or restrictions at a national level

European Union / European Economic Area

SUD REPROCESSING FROM DATE OF APPLICATION ON

Date of application of MDR

- MDR is binding and directly applicable in all EU/EEA Member States
- Directives such as 93/42/EEC will be repealed
- Amendments of the national law (MDR provisions override national law)
- SUD reprocessing according to MDR and according to CS

  or in case of absence of such CS: accordance with any relevant harmonised standards and national provisions that cover the aspects stated in Art. 17(3) sub-paragraph (b)

Date of application of MDR

- Is the EU keeping the patchwork?
- At the moment **YES!**
- And later? **TIME WILL TELL**

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Prospects

WHAT IS COMING SOON?

- EC: **Implementing Regulation** on Common Specification for the reprocessing of SUD
- Preliminary Draft already prepared (not publicly available, confidential)
- Obligations and responsibilities
- List of SUD considered non-reprocessable
- Conditions of the SUD reprocessing, QM system, certification
- Incident reporting
- Tracking system
- Documentation

- **Can we spot trends in national legislation with respect to Art. 17 MDR?**
- **Hardly. Just unreliable forecasts!**
- **My own opinion!**

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- **Germany** 2020 forecast: SUD reprocessing will be permitted by law, including SUD reprocessing and using within a health care institution including reprocessing by service providers on behalf of health care institutions; CS for SUD reprocessing - RKI/BfArM Guideline for MUD reprocessing DE
- **Belgium** 2020 forecast: similar to Germany BE
- **Netherlands** 2020 forecast: similar to Germany NL
- **UK** 2020 forecast: No EU Member State, SUD reprocessing as a manufacturer will be permitted by UK Law GB
- **France** 2020 forecast: SUD reprocessing prohibited. FR**Permanently?**

Summary of the key messages

- **SUD reprocessing regulated by Art. 17 MDR (May 26th 2020)**
- **EU/EEA Member States have various options**

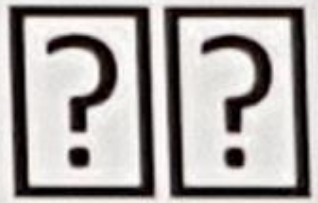
  #1 SUD reprocessing as a manufacturer

  #2 SUD reprocessing and using within a health care institution or – as a ser-vice provider – reprocessing on behalf of such a health care institution – CS!

  #3 Total or partial ban of SUD reprocessing
- **MDR is binding and directly applicable in all Member States**
- **EU is keeping the patchwork! Unreliable forecasts at the moment!**

THANK YOU FOR YOUR ATTENTION!

ANY QUESTIONS?



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