wfhss
World Federation for Hospital Sterilisation Sciences

SGSV
SSSH
SSSO
Schweizerische Gesellschaft für Sterilgutversorgung
Société Suisse de Stérilisation Hospitalière
Società Svizzera di Sterilizzazione Ospedaliera

Increasing patient safety by validating a reproducible method for reprocessing ultrasound probes

Part 2

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Legal aspects

European Union level 	**European Medical Devices Regulation** • MDR (**M**edical **D**evice **R**egulation) • (General provisions)

National level 	• MPDG (**Medical Devices Implementation Act**)
	  • (Penal Code)
	• MPBetreibV (**Medical Devices Operator Ordinance**)
	  • (Detailed requirements)
	• (IfSG) **Infection Protection Act**
	  • (Prevention and control of infectious diseases)

Sub-legislative level	• Standards (DIN-EN-ISO)
	• Guidelines:
	  • **Guideline of** the Commission for Hospital Hygiene and Infection Prevention (**KRINKO**) at the Robert Koch Institute (**RKI**) and the Federal Institute for Drugs and Medical Devices (**BfArM**) "**DGKH/RKI/BfArM**".
	  • Scientific societies (DGSV/SGSV/ÖGSV)
	  • Detailed instructions for practical use
	• Regulations/Rules
	  • UVV (Accident Prevention Regulations)
	  • BGR (Employer's Liability Insurance Association Rules)
	  • BGV (Employer's Liability Insurance Association Regulations)

Legal aspects

- **MDR**

- 11. infection and microbial contamination

  - 11.1 Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons.

  - 11.5 Devices labelled as 'sterile' shall be processed, manufactured, packaged and sterilised by means of appropriate, validated methods.

Prevention measures!

- Protection against Infection Act (IfSG) § 23 Para. 3

Require-ments

- (3) The heads of the following facilities shall ensure that the **necessary measures are taken** in accordance with the state of the art in medical science,

Goal

to **prevent healthcare-associated infections** and avoid the **spread of pathogens, especially those with resistance:**

- Hospitals,
- Outpatient surgery facilities,
- Day Hospitals,
- Maternity facilities,
- Medical practices, dental practices,
- …

Legal aspects

- Medical Devices Operator Ordinance §8.1
  - (1) The reprocessing of medical devices intended to be used disinfected or sterile shall be carried out, ***taking into account the manufacturer's instructions,*** using ***suitable validated procedures*** *in* such a way that the success of these procedures is **ensured and *traceable***

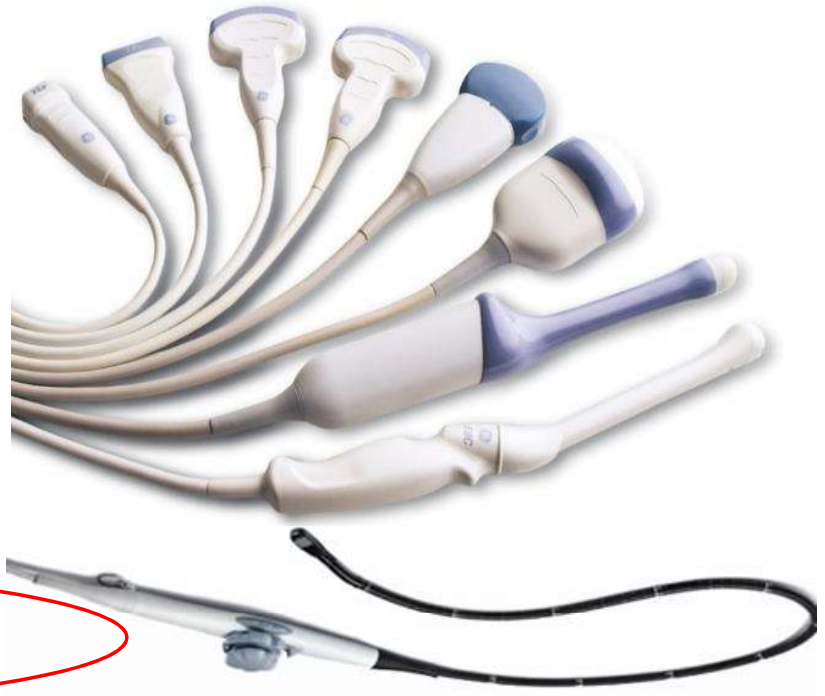
Require-ments

Goal

and the ***safety and health of*** patients, users or third parties is ***not endangered***.

Ultrasound probes

- Risk assessment and classification
  - Diagnostics
    - Semi-Critical
  - Intraoperative
    - Critical
- Grouping
  - Group A
- Characteristics
  - Sensitive to liquids and heat!



Established procedures

- Wipe disinfection procedure with:
  - Disposable cleaning wipes + Disposable disinfecting wipes

- Semi-automatic cleaning and disinfection process with „validatable high-level disinfection process“

RKI publication

❖ 20.11.2020 Publication of a technical explanation by the Robert Koch Institute with the following key statements

- *"...a validability of the final disinfection of semi-critical medical devices with wipes is currently ... not given"*
  - ➢ Manual wipe disinfection cannot be validated
- *"The RKI is not aware of any guideline or standard that could serve as an adequate basis for ensuring this requirement."*
  - ➢ Lack of validation guidelines
- *"German law requires on-site validation as part of the mandatory validation requirements for reprocessing semi-critical medical devices."*
  - ➢ The Robert Koch Institute points out that a validated process must be generated by the operator for both Automated and manual reprocessing of medical devices.

Established procedures

- Wipe disinfection procedure with:
  - Disposable cleaning wipes + Disposable disinfecting wipes

X

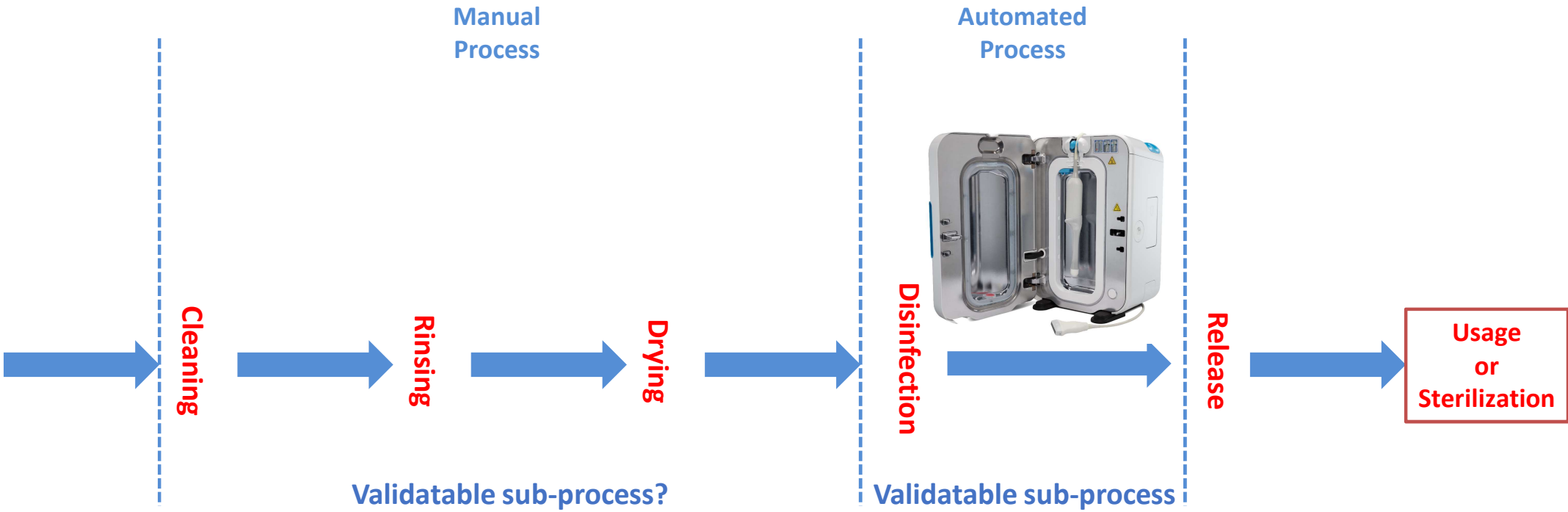
Wipe disinfection as a procedure?

- Semi-automatic cleaning and disinfection processes with “validatable high-level disinfection process”

Currently the only validatable method or alternative to wipe disinfection.

Semi-automatic process

Sequence of a semi-automatic cleaning and disinfection process



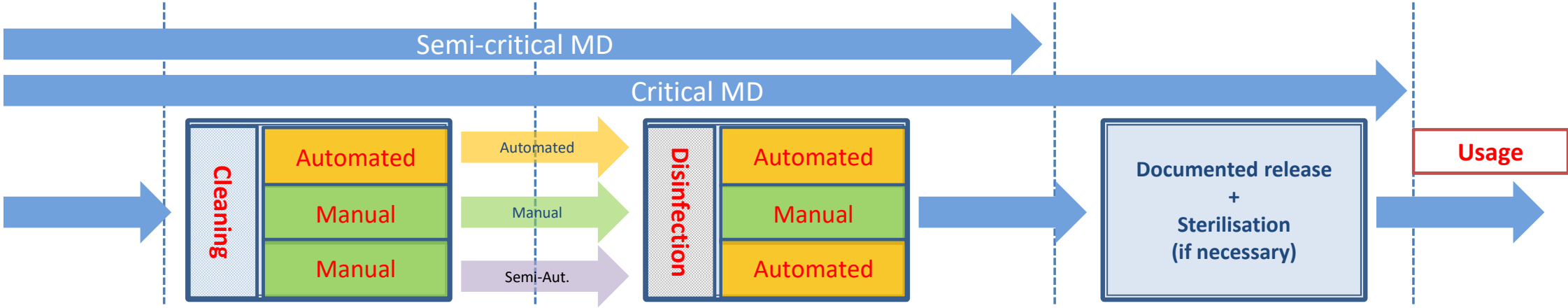
Is the validation of the automatic disinfection device or the "disinfection process" sufficient to consider the entire process as a validated process?

No!

Processing method

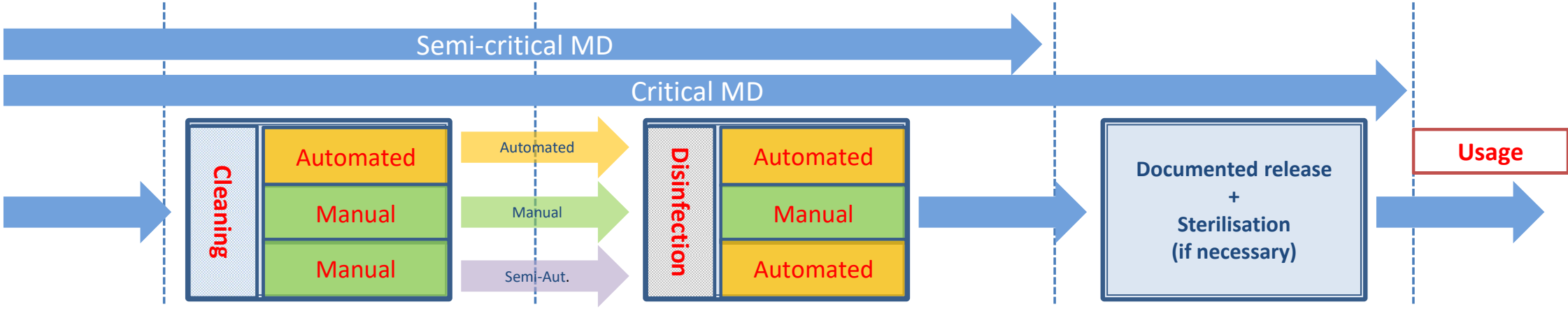
- **Cleaning and disinfection procedures**

  - Purely automated process: automated cleaning and automated disinfection process
  - Purely manual process: manual cleaning and manual disinfection process
  - Semi-automatic process: manual cleaning process and automated disinfection process



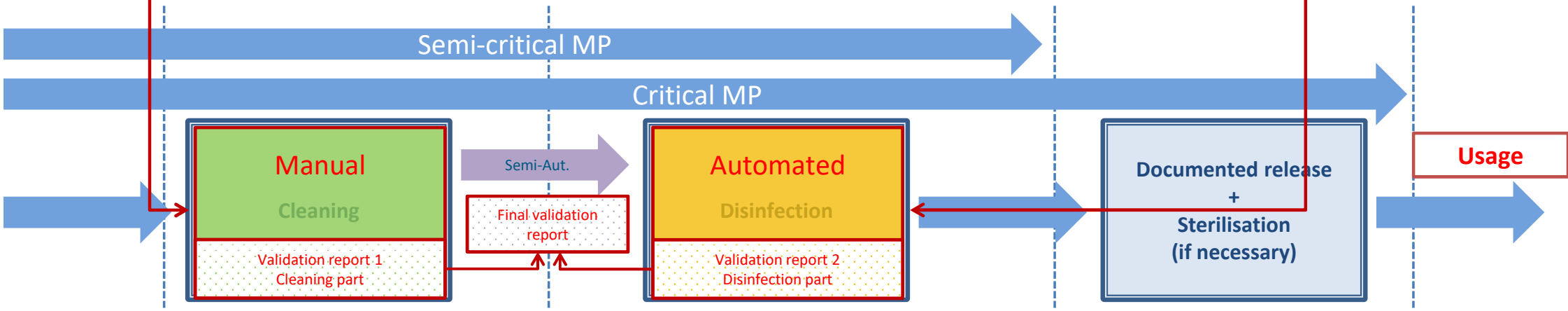
Validation basics

- **Validation Guidelines**
  - **Automation:**
    - "Guideline of DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices".
      - DIN EN ISO 14971, DIN EN 15883 and DIN EN ISO 17664
  - **Manual:**
    - "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices".
      - DIN EN ISO 14971, DIN EN 14885 and DIN EN ISO 17664



Validation of a semi-automatic process

- **Validation principles of a semi-automatic cleaning and disinfection process**
  - **Automated:**
    - "Guideline of DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices".
    - DIN EN ISO 14971, DIN EN 15883 and DIN EN ISO 17664
  - **Manual:**
    - "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices".
    - DIN EN ISO 14971, DIN EN 14885 and DIN EN ISO 17664



Validation results

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Prüfbericht zur Auftragsnummer A2021016392 vom 27.09.2021

Auftrag

Auftragsnummer	A2021016392	Kundennummer	11857
Prüfung	Validierung manuelle Aufbereitung - Desinfektionsprüfung		
Probenstelle	Endoskopie		
Probenehmer	HYBETA GmbH	Probenahmedatum	21.09.2021
Hersteller/Gerätetyp		Seriennummer	
Art der Aufbereitung	maschinell, manuell	Desinfektionsmittel	
Referenznummer			

Prüfung

Eingang	23.09.2021	Prüfbeginn	23.09.2021	Prüfende	27.09.2021	Freigabe	27.09.2021

Prüfergebnisse

Probenummer	A2021016392-001	Material	Tupfer
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Probenummer	A2021016392-002	Material	Tupfer
Lokalisation			
Parameter		Wert	Einheit
Keime		kein Keimwachstum	

Probenummer	A2021016392-003	Material	Tupfer
Lokalisation			
Parameter		Wert	Einheit
Keime		kein Keimwachstum	

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Beschreibung	R3		
Parameter		Wert	Einheit
Restprotein		< 5	µg

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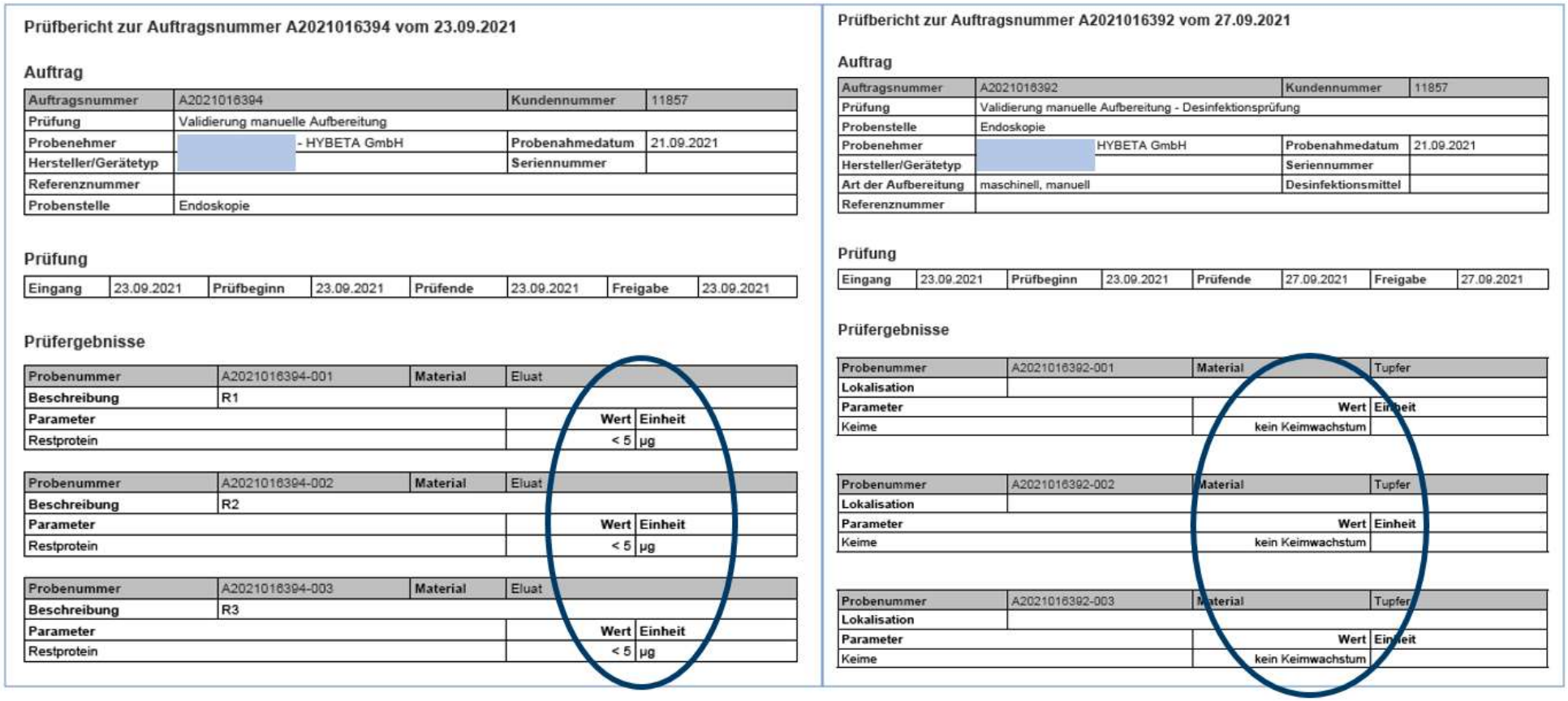

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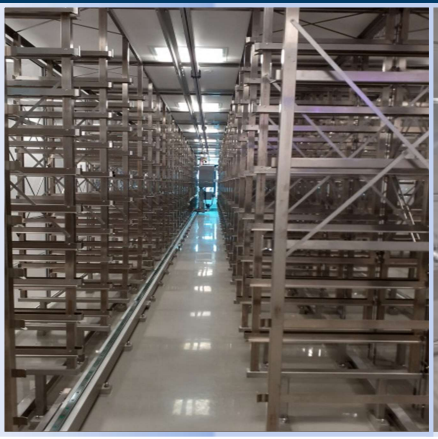


Thank you for your attention!

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