

Validation of cleaning and disinfecting processes in WDs: Implementation of the ÖGSV- Guideline

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Processing of instruments

- ✦ preferably automated thermal processes

 - Washer-disinfector



- ✦ Within the procurement of new instruments suitability for an automated process should be a determining criterion



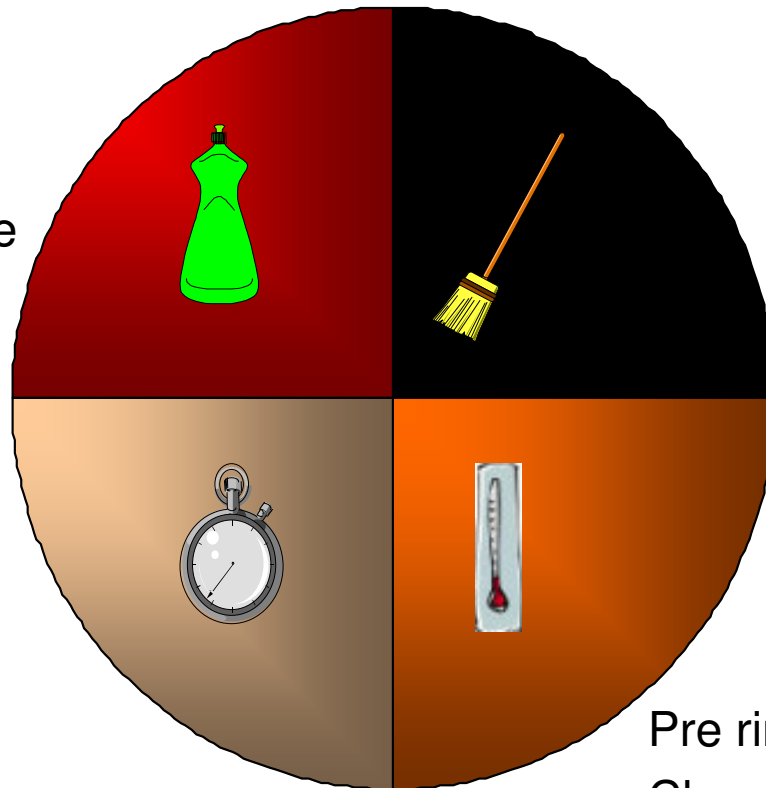
Automated cleaning and disinfection

✱ Cleaning efficacy depends on:

- kind of MD
- kind of contamination
- professional loading (right position, no overloading, no obstruction of the moving parts etc.)
- correct service (e.g. cleaning of nozzle and sieves)
- cleaning process in WD (mechanics, chemicals, time, temperature)

Influencing factors – cleaning efficacy

detergents
dosing
water quality
dosing temperature
foam performance



pump pressure
conveying quantity
chamber geometry
flow conditions
Washing arms
trays
water quantity
dosing temperature
foam performance

heating up
cleaning
last rinse

Pre rinse
Cleaning
Last rinse



ÖNORM EN ISO 15883 Part 1-5

Washer-Disinfectors

- ✦ Part 1: General requirements, definitions and tests
- ✦ Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware etc.
- ✦ Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste container



ÖNORM EN ISO 15883 Part 1-5

Washer-Disinfectors

- ✖ Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes
- ✖ Part 5: **CEN ISO/TS 15883-5**: Test soils and methods für demonstrating cleaning efficacy


Validation

- ✂ „*Documented procedure for obtaining, recording and interpreting data required to show, that a process will comply consistently with predetermined specifications*“
- ✂ Validation should confirm the conformity of the processes in the WD with the given specifications as well as the qualification of the process for the MDs used on site
- ✂ ÖNORM EN 15883: Validation = entire programme, consisting of
 - Installation qualification (IQ),
 - Operation qualification (OQ) and
 - Performance qualification (PQ)



Validierung

- ✖ Validation of reprocessing is the **verification** of the process being suitable for defined products in defined packages and load configurations to meet the intended efficacy
- reproducible** under the conditions on site (i.e. is able to bear clean, disinfected and - if applicable - sterile products)



ÖGSV-guideline to validation

www.oegsv.com

- ✚ describes principles for validation, revalidation and routine control of reprocessing in WDs meeting the standard
- ✚ also applicable to non-conform WDs
- ✚ **Text of guideline**
- ✚ **Annex 1:** Test method und contents
- ✚ **Annex 2:** Report
 - Part 1: Commissioning protocol
 - Part 2: Test protocol for OQ and PQ
- ✚ **Annex 3:** Procurement



Preconditions for validation

- ✂ structural requirements
- ✂ qualification of staff
- ✂ adequate quality assurance/quality management
- ✂ risk evaluation and classification of MD and MD-groups
- ✂ technical minimum requirements for WDs
- ✂ supply of resources (e.g. demin. water)



Operative Preconditions

- organisation chart
- information of the WD manufacturer (e.g. calibration protocols, program specifications)
- instruction manual for the WD
- instructions of the MD manufacturer for reprocessing
- information of the manufacturer of the process chemicals
- load configurations
- standard instructions for all steps of reprocessing
- risk classification according RKI
- operation journal
- hygiene plan (incl. Cleaning/disinfection-plan)
- maintenance plan
- routine control plan
- evidence of qualification resp. education
- Criteria for product release and -documentation

Minimum requirements for WD

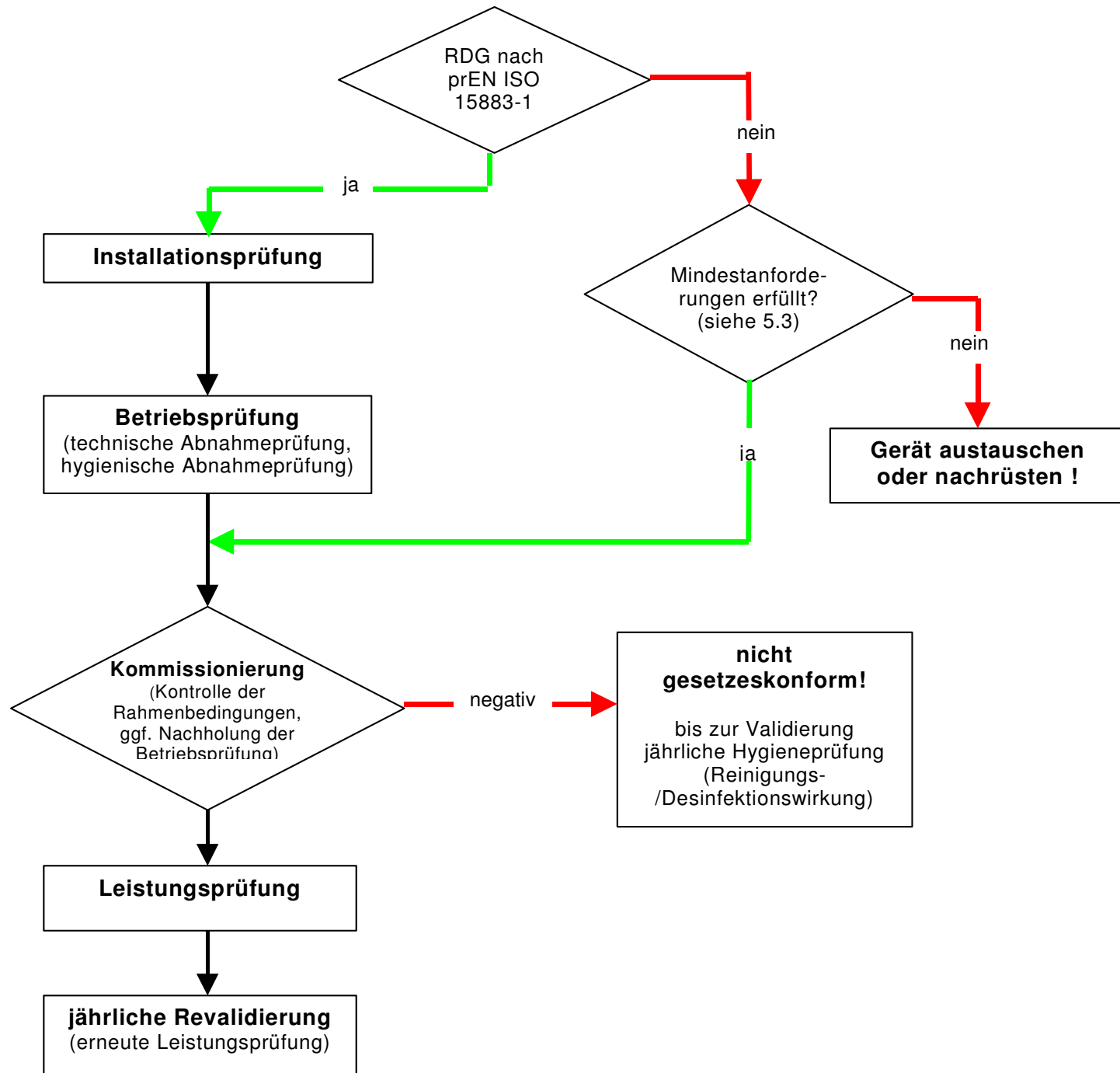
- ✦ Automatic cycle (freely programmable programmes)
- ✦ Adjustable temperature display
- ✦ Automatic dosing of chemicals
- ✦ permanent fault indication
- ✦ Cycle counter (or documented control system)
- ✦ Process documentation (minimum: temperature / time parameters as actual values, date, time)
- ✦ suitable load carriers for MIS instruments, anesthetic equipment, if applicable



Prüfung/Validierung

Type test / Works test			
VALIDATION	Installation Qualification (IQ)		
	Operation Qualification (OQ)	technical inspection	
		hygienic inspection	
	Validation in the more specific sense	Commissioning (Assessment of structural. technical preconditions (if applicable: repetition of specific tests of OQ))	
		Performance Qualification	
Routine control and annual revalidation (re-qualification)			

validation



Type test/ Works test (Manufacturer)

☼ Type test:

- ➔ Sequence of tests to determine process parameters for a certain type of WD



☼ Works test:

- ➔ Sequence of tests, carried out on a single WD at the manufacturing site to provide evidence of the accordance with it's specification

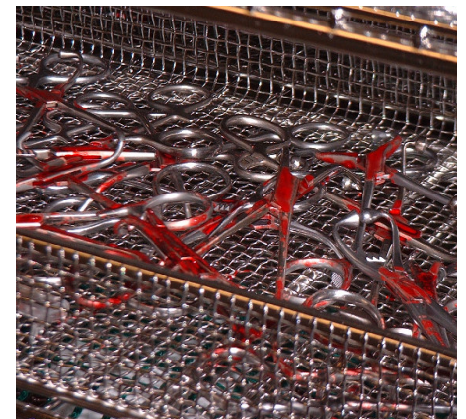
IQ / OQ

✱ Installation Qualification (responsibility of the manufacturer)

- Inspection, if the WD was delivered, installed and supplied with resources according to the contract and the device is safe for operation

✱ Operation Qualification (responsibility of the manufacturer)

- technical inspection (evtl. in combination with IQ)
- hygienic inspection





OQ: Technical Inspection

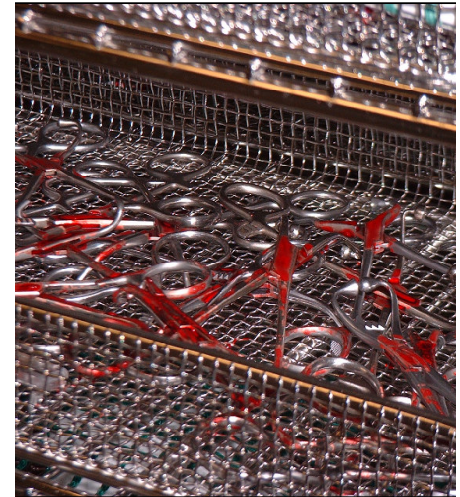


Checking of:

- documentation
- doors and interlocks
- resources supply
- safety features and equipment (e.g. doors and interlocks)
- construction (finish) (e.g. welded seams)
- display and recording instrumentation (calibration)
- if applicable: further technical specifications
(e.g. in accordance with tendering)

Hygienic Inspection

- ✖ In responsibility of the manufacturer
- ✖ preferably independent hygiene expert
- ✖ in case of positive result of IQ and OQ the preconditions for taking-over of the device by the institution is given
- ✖ For problems during PQ due to MDs or load configuration used on site the manufacturer is out of responsibility, unless there exist other contract details



Prüfanschmutzung Schafblut

OQ: Hygienic Inspection- Austrian Test Method (CEN ISO/TS 15883-5)



Cleaning efficacy

(standard soiling)

- Chamber (KMNE)
- load carrier (KMNE)
- load (3x)
(MNE, reactivated sheep blood)



**Disinfection efficacy,
temperature control,
reproducibility (thermoelectric)**

- chamber walls
- load carriers
- load



Accuracy of display/recording

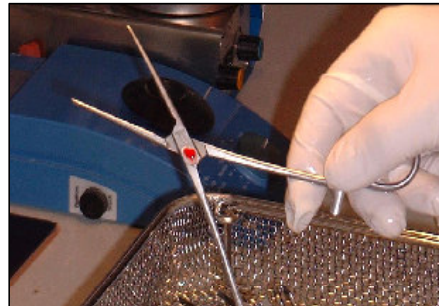


dosing accuracy



water quality

- softened water
- deionised water
- last rinse water
 - chemical/physical
 - pH, conductivity, hardness, Chlorine
 - (bacteriological)



Test method surgical instruments

- ✂ Test soil: reactivated sheep blood
- ✂ application of TS with brush
 - critical spots (joints)
- ✂ Drying app. 2 x 30 min
(upside down)
- ✂ Interruption after Cleaning!
- ✂ Repetition 3 x



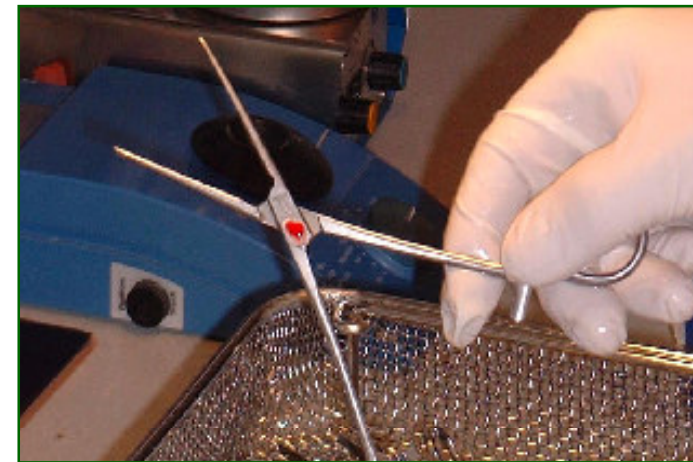
Evaluation surgical instruments

✱ Evaluation

- Visual check
- Protein detection (if necessary)

✱ Criteria for acceptance

- Max. 5 % of soiled instruments may show residual soiling
- Protein detection: within acceptance criteria
(20 µg/ Instrument)





Validation

✂ Commissioning:

- technical, operational and organisational preconditions as well as documentation is checked

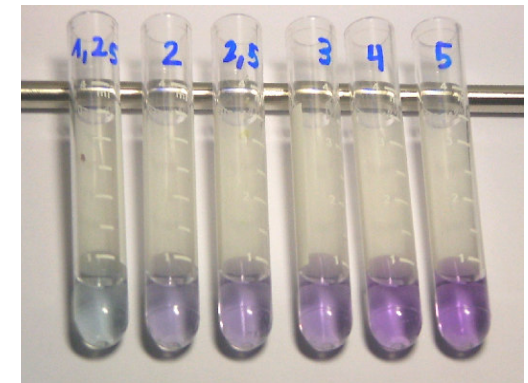
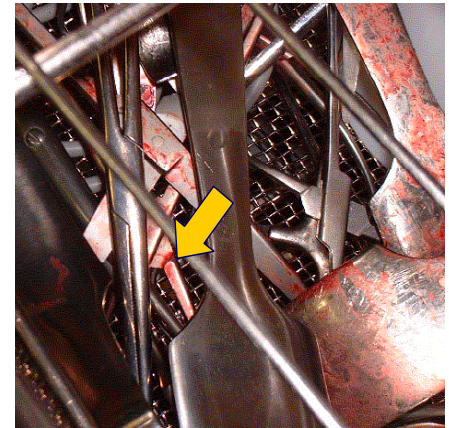
✂ Performance Qualification:

- the process is checked for its efficacy and reproducibility,
- that means....

Performance qualification

Cleaning efficacy is tested under real conditions with:

- the MD to be reprocessed
- the specified load configurations (preferably worst case)
- the specified program sequence
- the available resources
- the chosen detergents
- evaluation by protein detection tests
limit: 20 µg/instrument





Practicability of the Austrian test method

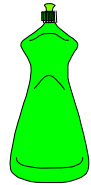
- ✂ Easy to accomplish
- ✂ Soiling on-site
- ✂ Analysis (visual control) possible without further effort
- ✂ Faults/deficiencies/problems (e.g. dosing of detergents, insufficient water quantity etc.) can be detected and solved – followed by a control survey

Problems in practice

- chamber geometry
- washing arms (construction/velocity)
- pump pressure (foam performance)
- water quantity
- load carrier (condition of water flow)
- trays



- detergents (high-/low-alkaline/neutral)
- foam performance
- dosing temperature
- dosing quantity
- dosing pumps (-tubes)
- water quality





Summary -1

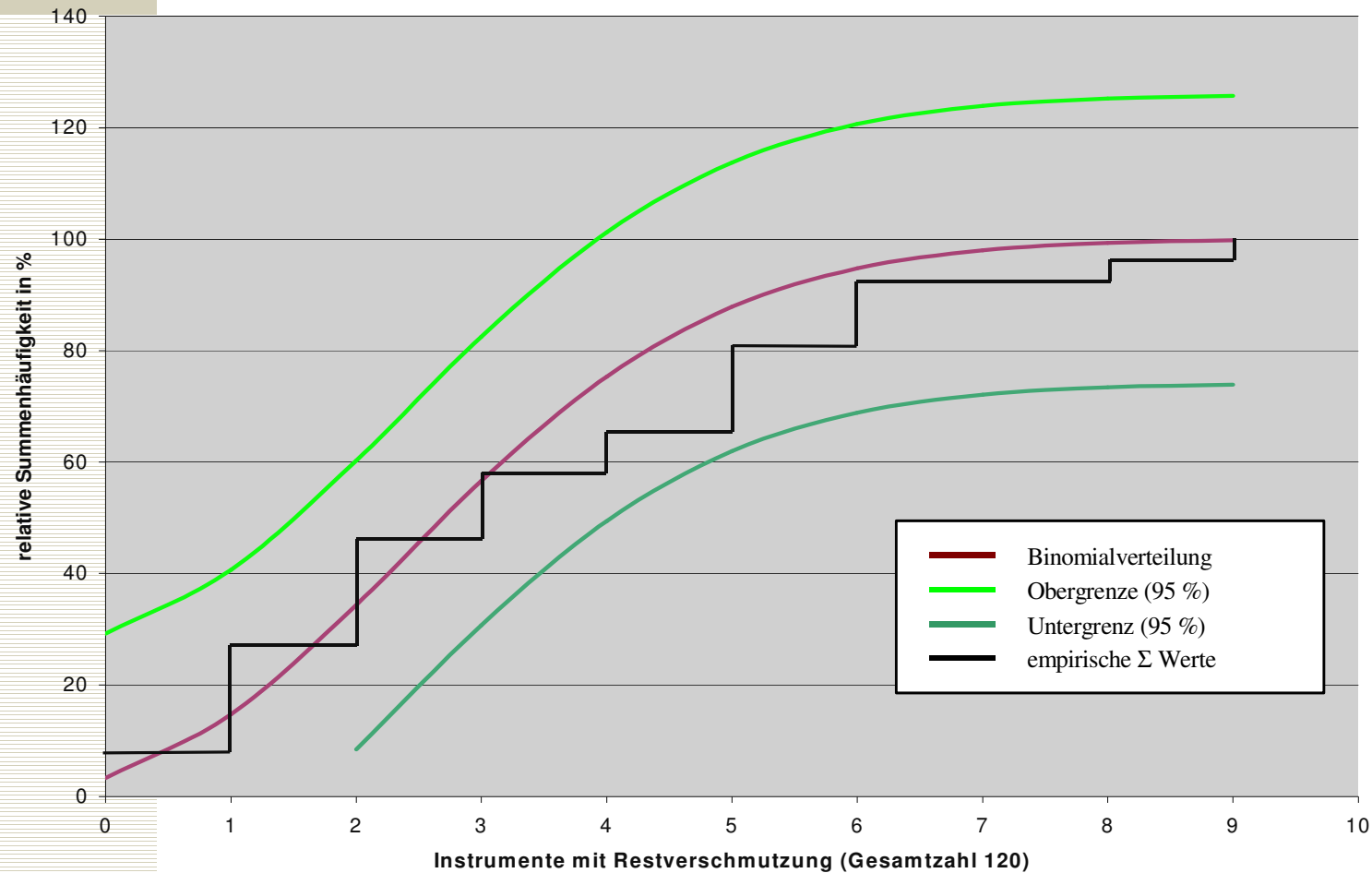
- ✦ The evaluation of the Austrian test method for WD-testing (especially for surgical instruments) showed, that it is suitable for an adequate process assessment.
- ✦ The averaged results are confident indicators for the efficacy of the tested cleaning process



Summary - 2

- ✦ Compliance with the 5% limit guarantees satisfying cleaning results during routine operation
- ✦ Protein detection tests on instruments with real contamination show consistently results below the defined acceptance criteria of 20 µg/instrument
- ✦ Good repeatability

Reproducibility of the Test Method





Summary - 3

- ✱ The implementation of new test methods (e.g. the new Austrian one) is an important part of the quality improvement in the field of reprocessing of medical devices and is finally able to help raising patient safety.



Thank you for your attention!