Procurement of WDs

(Washer-disinfectors)

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Background

- A lot of different products are on the market
- Operators of AEMPs (Processing Units for Medical Devices, PUMD) are not on the current level of requirements for WDs
- Important points are not mentioned in tenderings
General information

- Worked out
  - Expert committee for Testing of the ÖGSV (Austrian Society for Sterile Supply)

- Result
  - Annex 3 to the „Guideline for Testing, Validation and Routine Control of Automatic Washing-Disinfection Processes for Medical Devices“

- Purpose
  - Support for the operator
ANHANG 3
zur
Leitlinie
für die Prüfung,
Validierung und Überwachung
von
maschinellen Reinigungs- Desinfektionsverfahren
für Medizinprodukte

in Anlehnung an
prEN ISO 15883 Teile 1, 2 und 5

Beschaffung von RDG
Procurement of WDs

Required Information of the Type Test for the Operational Qualification / Validation

Recommendation of the ÖGSV for the Equipment of WDs
Basic Principles

- Buy only norm conform WDs
- Norm conformity with EN ISO 15883 part 1 and 2 has to be proved by the manufacturer
The following experts and departments have to be involved in the compilation of a contract specification:

- Employees of the PUMD
- Technical department
- Hygiene
- Occupational safety
- Person in charge of an external processing unit (if applicable)
The operator has to inform about

- Number and dimension of the WDs
- Provided space
- Provided equipment
- Favoured process-chemicals
- Type of the medical products to be processed
- Number and type of load carriers
- Type of loading and unloading
- Type of doors
Informations needed

- Instructions for processing of the Manufacturer of the MP (ÖNORM EN ISO 17664)
- Information of the Supplier of the WD
- Information of the Supplier of the process-chemicals
- Information of the Supplier of external dosing units (if applicable)
- Planner‘s information (if applicable)
  - sanitary, ventilation, statics etc.
Procurement of WDs

Settlement of the project
- Is the capacity sufficient?
- Interface to subcontractors?
- Construction – control by the supplier
- Delivery periods
- Installation periods
- Utilisation restriction during installation
- Time for installation qualification
- Time for operational qualification
- Reserved time for regular operation
Procurement of WDs

- Installation settings
  - Required space
  - Delivery time
  - Installation time
  - Statics at the installation site
  - Effects from/to adjoining rooms
  - Costs
  - Expenditure of time
  - Responsibility
Procurement of WDs

Installation of essential resources

- Water
- Deionised water
- Electricity
- Process chemicals
- Steam (if applicable)
- Compressed air (if applicable)
Procurement of WDs

- Supply- and disposal connections
  - Wastewater
  - Connections for process chemicals
  - Sampling ports
  - EDV circuit points
  - Emergency stop switch
Procurement of WDs

- **Process documentation – Required**
  - Setpoint- and actual value for temperature, dosage, water amount
  - Batch number
  - Date, time
  - Programme number and name
  - Machine number
  - Fault report
  - Operator, MP, load carrier (if applicable)
Procurement of WDs

- Device-documentation (to be provided by the WD manufacturer)
  - Documents of the Type testing
  - Documents of the Works test
  - Test report of the installation test
  - Instruction sheet
  - Maintenance guideline
  - Device book (MP-book)
  - Process parameters incl. tolerances
  - Water quality requirements
Procurement of WDs

- Additional provided information by the manufacturer
  - Batch time
  - Upgrading possible
  - Easy handling possible
  - Easy changing of chemical containers possible
  - Connection possibilities for MPs
  - Process surveillance possible
  - Surveillance of washing arms
  - Separation of regulation- and measuring sensors
Procurement of Washer-disinfectors

Required Information of the Type Test for the Operational Qualification / Validation

Recommendation of the ÖGSV to the Equipment of WDs
Data from the type test

- Summary of the following data
  - Device type
  - According to which version of EN 15883 was tested (draft?)
  - Executing test centre
  - Date of type test
Data from the type test

Cleaning efficiency
- Number of tests
- Programme interruption at which step?
- Programme specifications
- Used Process chemicals
- Used water quality and amount
- Pump pressure
- Load carrier
- Used auxiliary means
Data from the type test

- Cleaning efficacy
  - Test load
  - Test soil
  - Results of the optical evaluation
  - Results of protein detection tests
  - Measured and documented process data
  - Evaluation
  - Restrictions (if applicable)
Data from the type test

- Thermal disinfection efficacy
  - Number of tests
  - Programme specifications
  - Load carrier
  - Test load
  - Number and position of temperature sensors
  - Results of measurements
  - Comparison of the display with data of the measurement system
  - Measured and documented process data
  - Evaluation
  - Restrictions (if applicable)
Chemo-thermal disinfection efficacy

- Number of tests
- Programme specifications
- Disinfectant
- Dosage
- Test method
- measured and documented process data
- Evaluation
- Restrictions (if applicable)
Data from the type test

- Planned:
  - Summary of the type test is sent to the expert committee of the ÖGSV
  - Type tests are only accessible for auditors
  - List for users on the homepage
    - From which WDs type test results are available
Procurement of Washer-disinfectors

For the Operational test / validation needed information from the type testing

Recommendation of the ÖGSV to the equipment of WDs
**Recommendation**

- **Helpful for the user**
  - Easily dismountable washing arms and tubes on the loading carriers
  - Glass door
  - Chamber illumination
  - Lifting support for loading carriers
  - Surveillance of washing arms
  - Tight fitting of filters
  - Steam heating
  - Temperature display
Recommendation

- **Helpful for users and auditors**
  - Printout of the setpoint and actual values of the temperatures, water amount and process chemicals
  - Display and printout of the pump pressure
  - Hygiene test programmes
  - Possibility of external testing of the pump pressure
  - Sampling ports at the supporting water pipes
  - Sampling ports at the pumping system
Recommendation

- Rather disadvantageous for the user
  - Reprocessing cycles without pre-rinse
  - Reprocessing cycles without water change between the cleaning and the disinfection stages
  - Reprocessing cycles without intermediate rinsing between the cleaning and the disinfection stages
  - Programmes with reduced water consumption
  - Programmes, which cannot be modified
Thank you for your attention!