

Procurement of WDs

(Washer-disinfectors)

HFK Andrea Percht
MicroMed KEG Linz



■ 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



■ 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



ÖGSV

Österreichische Gesellschaft
für Sterilgutversorgung

A-8045 Graz, Ursprungweg 160
Tel: 0316/69 47 11, Fax: DW 4

email: office@oegsv.com
Internet: www.oegsv.com

|

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 conformitiy 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.

- **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

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

- **Installation of essential resources**
 - Water
 - Deionised water
 - Electricity
 - Process chemicals
 - Steam (if applicable)
 - Compressed air (if applicable)



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



- **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)

- **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

- **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

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

Dokumentation der Typprüfung für das Miele Reinigungs- und Desinfektionsgerät G 7823/24		Miele PROFESSIONAL
DIN/ISO 15883-1:2006	Stand: 2006-07	Seite 1 von 58
Version 1.02	Datum: 17.08.2006	

**Dokumentation
der Typprüfung
gemäß
DIN EN ISO 15883-1
für die Miele
Reinigungs- und
Desinfektionsautomaten
G 7823 und G 7824**

- **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

- **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)

- **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)

■ 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



Herzlich Willkommen auf der Internetseite der
Österreichischen Gesellschaft für Sterilgutversorgung



[Wer wir sind...](#)
[Was wir wollen...](#)
[Wie Sie Mitglied werden...](#)

Kontakt:
ÖGSV
Ursprungweg 160
8045 Graz
Tel: +43(0)316/694711
Fax: +43(0)316/694711-4
email: office@oegsv.com


Internationaler Kongress
zur Aufbereitung von Medizinprodukten
 
3. – 5. Mai 2007 in Baden bei Wien
[Zur Kongress-homepage](#)

[Impressum](#)

- Procurement of Washer-disinfectors
- For the Operational test / validation needed information from the type testing
- **Recommendation of the ÖGSV to the equipment of WDs**

- **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

- **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

- **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!**