3 Years Experience With Certification of Reprocessing Based on the German RKI/BfArM Recommendation - A Field Report

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Legal Basis in Germany

- The Act on Medical Devices (MPG)
  - §14 Installation, operation, use and maintenance of medical devices
  - DIN EN ISO 13485
    - Section 1.4 Quality assurance ...
  - RKI-BfArM Recommendation
    - §4 (2) Maintenance
  - „Medical Device Operation Regulation“
## Classification (RKI/BfArM-Recommendation)

<table>
<thead>
<tr>
<th>Properties of the medical device (design, material)</th>
<th>Type of use (prior, subsequent)</th>
<th>Type of contact</th>
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<tbody>
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<td>noncritical</td>
<td></td>
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<tr>
<td>without particular requirements A</td>
<td></td>
<td></td>
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<tr>
<td>increased requirements B</td>
<td>(WD) Steam sterilization QA</td>
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<td>maximum requirements C</td>
<td>Qualification WD</td>
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<tr>
<td>maximum requirements C</td>
<td>not defined</td>
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Accreditation of the Certification Body

- Certification according to DIN EN ISO 13485 combined with the RKI/BfArM Recommendation in Germany only allowed for accredited Certification Bodies
- Accreditation performed by the Central Authority of the German Federal States for Health Protection (ZLG)
- Intention: professional competence
  - for products and their reprocessing requirements
  - for reprocessing processes
- First accreditation 3 years ago
- Currently are three Certification Bodies accredited:
  - 2 for medical devices up to and including „critical C“
  - 1 for medical devices up to and including „critical B“
Considered Certification Projects

Number of Audits

- 2003/2004
- 2005
- 2006

Risk evaluation

- up to and including „critical B“
- up to and including „critical C“

Percentage of hospitals

- 1,5%

Dr. Thomas Kiessling, 05.05.2007
Strengths of the QA Systems (1/3)

- Documents of the QA systems in general in good condition
  - A few systems were set up completely independently by the hospital
  - Often assistance by external consultants
  - Rarely adjustment needed

- In all cases a risk evaluation according to the RKI/BfArM Recommendation was performed, but different proceedings:
  - Individual evaluation of each medical device
  - Evaluation based on groups
  - Overall evaluation
  - Use of the „decision tree“ compiled by the German Society for Sterile Supply (DGSV)
  - Results reported in charts (printout) or electronically in a database
Strengths of the QA Systems (2/3)

- Requirements for reprocessing of particular medical devices were defined in
  - Documents of the QA system (e.g. work instructions)
  - Packing lists / object lists (for sets of medical devices)
  - Usually a combination of both

- For personnel qualification in all cases the training programme of the DGSV (EFHSS) was taken into consideration:
  - Staff (level I training)
  - Supervisor (level II training)
  - Facility manager (level III training)
  - Staff member without any training courses were only allowed to work under supervision in a limited range of function
Strengths of the QA Systems (3/3)

- In many cases the work flow was supported by a specific IT system
  - Control of packing lists / object lists (for sets of medical devices)
  - Labelling
  - Assignment of the medical devices to sterilization batches
  - Traceability
  - Recording of process data

- Validation of steam sterilization (EN 554)
  - Hardly any discrepancies, hardly any observations
  - Performed by manufacturer, more and more by independent test laboratory
  - Very differing extent and quality of the validation reports
Weaknesses of the QA Systems (1/3)

- Validation of processes, routine control
  - Washer-disinfectors (EN ISO 15883) (tendency: much better quality during the last 6 months)
  - Low temperature sterilization processes, especially $\text{H}_2\text{O}_2$ plasma process (EN ISO 14937, EN 15424, EN 550)
  - Sealing process (EN ISO 11607-2)
  - Often caused by a lack of experience (validation lab, manufacturer and operator) how to realize the requirements from standards

- Expertise of the validation lab
  - Many times an interpretation of results is missing
  - Partially validation reports are incomplete (missing test results, missing checkpoints, missing entries and signatures)
  - Partially test results were misinterpreted
Weaknesses of the QA Systems (2/3)

- Manufacturers’ instructions
  - For complex medical devices often the needed manufacturers’ instructions are not available
  - Some manufacturers’ instructions do not include utilizable information
  - When the proceeding differs from manufacturers’ instructions often a documented rationale is missing, including a risk evaluation and information on evaluation date and members of the evaluation team

- Risk analysis, risk management
  - Typically a risk analysis beyond the classification according to the RKI/BfArM Recommendation is not performed, even though several estimations are done (e.g. for manual cleaning and disinfection of containers for sterile products)
Weaknesses of the QA Systems (3/3)

- Hygiene
  - Rarely severe deficiencies, most observations are related to details (only one case with a severe lack of hygiene: reliable disinfection was not ensured, re-contamination was not prevented)

- Reliable function or use of IT systems, traceability
  - No proof of evidence for the correct function of the specific IT systems by software validation (complete and correct recording of process data, reproduction of data during long term archiving)
  - Insufficient adjustment of the IT systems and the working process results in a lack of documentation: several sterile devices were not assigned to any sterilization batch but delivered for use
Reprocessing of Single Use Devices

- RKI/BfArM Recommendation does not differentiate whether the manufacturer intended a single or a multiple use
- Single use devices are typically classified to be „critical C“
  - Certificate needed issued by an accredited Certification Body
- Manufacturers´ instructions for reprocessing are missing
  - Design and development of the complete reprocessing process must be done
  - Section 7.3 „Design and Development“ of DIN EN ISO 13485 must be covered within the QA system and is part of the certification process
  - Detailed evidence of suitability related to process qualification and safety of reprocessed devices is needed
  - High demands on traceability, amongst others back to manufacturers´ lot number
- In Germany only a very limited number of companies fulfil these criteria
Summary

- In Germany certification according to DIN EN ISO 13485:2003 combined with the RKI/BfArM Recommendation demonstrate a high level for the reprocessing processes.

- Room for improvement exist at:
  - Validation of particular processes
  - Manufacturers` instruction
  - Risk management
  - Software validation
Thank you for your attention!
I am looking forward to your questions
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