

Requirements to the Hygiene during Reprocessing of Medical Devices

Recommendation of the commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch-Institute (RKI) and the German Institute for Pharmaceuticals and Medical Devices (BfArM)

1 Basics

1.1 Responsibility

1.2 Requirements for Reprocessing

1.3 Validation of Reprocessing Procedures/Processes

1.4 Assurance of the Quality of the Reprocessing Processes to be used

2 Reprocessing Procedure

2.1 Reprocessing of unused Medical Devices

2.2 Reprocessing of used Medical Devices

2.2.1 Preparation of Reprocessing (Pretreatment, Collection, Precleaning, if necessary Demounting, Intermediate Storage and Transport)

2.2.2 Cleaning, Disinfection, Flushing and Drying

2.2.3 Test of the technical functional security

2.2.4 Packaging

2.2.5 Sterilization

2.2.6 Marking

2.2.7 Release for Use

2.2.8 Batch Documentation

3 Transport and Storage

Anlage 1 Definition „suitable validated procedures“

Annex 2 to Clause 2.2.3 Test of the technical functional security

Annex 3 Implementation and Operation of Washer-Disinfectors (WD) to reprocess Medical Devices (Checklist)

Annex 4 Implementation and Operation of Table-top Sterilizers to reprocess Medical Devices (Checklist)

Annex 5 Overview about Requirements to Reprocessing Units for Medical Devices

Annex 6 Technical knowledge of the Personnel

Annex 7 Measures to minimize the Risk of an infection with CJD/vCJD by Medical Devices

Annex 8: Requirements to the Hygiene during the Reprocessing of flexible Endoscopes and additional endoscopic Instruments