

# 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**