

# 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