Submission Form on the completeness of sterilization validation Documentation according to EN ISO 17664:2004 requirements

(If a specific point cannot be covered, EN ISO 17664 compliance may not be granted. If applicable: An explanation shall be documented how the EN ISO 17664 requirement is covered to meet the state of the art.)

Topic	Data	Source of documented evidence	Reference
Product to be reprocessed including short description (Product dimension, Packaging configuration, Dimensions)			
Are product families defined?			EN ISO 17664:2004 5

1 General description

Topic	Data	Source of documented evidence	Reference
Were validated cleaning, disinfection and sterilization processes used?			EN ISO 17664:2004 3.5, 4.3 EN ISO 15883-1:2006 6.1.3.1, EN ISO 17665-1:2006, EN ISO 11135-1:2007,

1.1 Design

Is a risk analysis available defining mitigation measures regarding reprocessing and information to be provided? 1. Was disinfectant evaluated for appropriateness regarding resistant organism under the intended use (e.g. mycobacteria, prions) 2. Was the process of reprocessing evaluated to usability errors?			EN ISO 17664:2004 3.1,3.6, 4.2 ,6 EN ISO 14971:2009 4.3

2 Reprocessing instructions

2.1 Preparation at the point of use

Are any provisions for transport, rinsing and storing of the device defined?			EN ISO 17664:2004 3.3
Is a maximum time defined after use and begin of reprocessing			EN ISO 17664:2004 3.3

2.2 Cleaning

Topic	Data	Source of documented evidence	Reference
If the product does not sustain automatic cleaning/disinfection is a respective statement and evidence therefore provided? Is a warning provided?			EN ISO 17664:2004 3.5
Are the following parameters defined:			
1. Cleaning equipment			EN ISO 17664:2004 3.5, 4.3 15883-2:2006 4.1.2
2. Concentration of process chemicals			EN ISO 17664:2004 3.5, 4.3

2.3 Disinfection

Topic	Data	Source of documented evidence	Reference
Is a validated non automatic disinfection process described?			EN ISO 17664:2004 3.6
Are the following parameters defined:			
1. Disinfection equipment			17664:2004 3.6, 4.3 15883-2:2006 4.1.2
3. Water quality			17664:2004 3.6

2.4 Drying (if applicable)

Topic	Data	Source of	Reference

		documented evidence	
Is drying necessary according to the IFU?			EN ISO 17664:2004 3.7
Were the following parameters investigated at validation:			EN ISO 17664:2004 3.7
3. What drying media was used (type, specification)			EN ISO 17664:2004 3.7, 3.1, 4.3

2.5 Maintenance (if applicable)

Topic	Data	Source of documented evidence	Reference
Are at any stage of the reprocessing cycle steps to ensure cleanness of the device necessary?			EN ISO 17664:2004 3.8
If inspection or maintenance is to be performed by a different party (manufacturer or authorized party) provisions for the conditions of cleanness and contamination of the device provided?			EN ISO 17664:2004 3.8, 3.1

2.6 Packaging

Topic	Data	Source of documented evidence	Reference
Is any specific containment			EN ISO 17664:2004

defined to be used with the product during sterilization?			3.9

2.7 Description of the sterilization cycle

Topic	Data	Source of documented evidence	Reference
Is a sterilization procedure defined?			EN ISO 17664:2004 3.10
Is specific equipment defined			EN ISO 17664:2004 3.10, 4.3

2.8 Device lifecycle testing

Topic	Data	Source of documented evidence	Reference
If the device is to be used in the central nervous system was a study performed to remove prions at cleaning? (is the risk of prion transfer to a patient evaluated, is data – including literature source- available showing by what reprocessing step the prion risk is reduced (log reduction))			EN ISO 17664:2004 3.5, 5 , 6