Product Service

Submission Form on the completeness of sterilization validation Documentation according to EN ISO 11135-1:2007 requirements

(If a specific point cannot be covered, EN ISO 11135 compliance may not be granted. If applicable: An explanation shall be documented how the EN ISO 11135 requirement is covered to meet the state of the art.)

General description

Topic	Data	Source of documented evidence	Reference
Product to be sterilized including short description (Product dimension, packaging configuration, dimensions)			7.1
If applicable: Mixed load upper and lower limit (details in sec (4.3)			9.4
SAL to be achieved			EN 556

1.1 Validation Approach

Validation approach according to equivalence consideration?			7.1.2, 9.3.1.3
Sterilization protocol available? Process specification available? If applicable: Are contractual agreements available?			10

2 Equipment characterization

2.1 Sterilizer etc.

Topic	Data	Source of documented evidence	Reference
Sterilization chamber name			6.2
Type sterilizer			6.2
Manufacturer sterilizer			6.2

2.2 Steam quality

Topic	Data	Source of documented evidence	Reference
Is the feed water/compressed air free of microbial contamination?			EN ISO 10993, MDD annex 1 8.3

3 Microbial Performance qualification

3.1 Bioburden, Endotoxins, cultivation

Topic	Data	Source of documented evidence	Reference
Microbial methods validation, bioburden trending data and maximum amount of bioburden accepted to enter the sterilization process.			7.3.1 Environmental control, 7.3.2 bioburden measurement required at defined intervals, B.1.4

			bioburden resistance in relation to BI. C.7 Max. bioburden of product presented to the sterilization cycle has to be defined. EN ISO 11737-1 A.4.4 Out of spec results.

3.2 BIs

Topic	Data	Source of documented evidence	Reference
organism			8.6a) have to comply to EN ISO 11138-2

3.3 PCD

Topic	Data	Source of documented evidence	Reference
Used full load of worst case product			9.5.4, 9.5.6 B.2

3.4 Short cycle

Topic	Data	Source of documented evidence	Reference
Was the BI resistance evaluated in relation to the natural			12.3.3, B.1.4 bioburden resistance

bioburden of the medical device?			in relation to BI OR C.8! test on sterility of products against viable PCDs EN ISO 11135-2 annex B

4 Physical Performance Qualification

4.1 Cycle Description and Data

Cycle Name: # 140							
minimum cycle parameter	**Set-point**	**Data PPQ cycle1**	**Data PPQ cycle2**	**Data PPQ cycle3**	**Data MPQ cycle1**	**Data MPQ cycle2**	**Data MPQ cycle3**
Sterilization							
Conditioning:							
Initial Vacuum level/rate	*mbar±mbar*						
Holding time under vacuum	*min±min*						
Chamber temperature	*°C±°C*						
Load temperature	*°C±°C*						
Chamber humidity/pressure	*% rH± % rH*						
Load humidity	*% rH± % rH*						
duration	*min±-min*						
EO injection/ dwell time:							
Chamber temperature	*°C±°C*						

4.2 Sensory system

Topic	Data	Source of documented	Reference

		evidence	
If parametric release is used: EO sensory system validation, humidity sensor system validation			6.2, 6.1.6, 9.5.5

4.3 EO residuals / Aeration

(7.2.3 EN ISO 10993-1ff ,7.2.4 EN ISO 10993-7)

Topic	Data	Source of documented evidence	
EO residuals determination according to what standard (with release date)			
EO method and conditions			EN ISO 10993-7 4.4.4 Extraction ratio is usually 1:2 to 1:10 g sample to extraction media. And 4.4.6 for Product extraction see ann D
ECH method and conditions			