

DIN EN ISO 11137-2:2013-09 (E)

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)

Contents	Page
Foreword	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms, definitions, and abbreviated terms	6
3.1 Terms and definitions	6
3.2 Abbreviated terms	8
4 Definition and maintenance of product families for dose setting, dose substantiation, and sterilization dose auditing	9
4.1 General	9
4.2 Defining product families	9
4.3 Designation of product to represent a product family for performance of a verification dose experiment or sterilization dose audit	10
4.4 Maintaining product families	11
4.5 Effect of failure of establishment of sterilization dose or of a sterilization dose audit on a product family	12
5 Selection and testing of product for establishing the sterilization dose	12
5.1 Nature of product	12
5.2 Sample item portion (SIP)	12
5.3 Manner of sampling	14
5.4 Microbiological testing	14
5.5 Irradiation	14
6 Methods of dose establishment	14
7 Method 1: dose setting using bioburden information	15
7.1 Rationale	15
7.2 Procedure for Method 1 for product with an average bioburden greater than or equal to 1,0 for multiple production batches	16
7.3 Procedure for Method 1 for product with an average bioburden greater than or equal to 1,0 for a single production batch	22
7.4 Procedure for Method 1 for product with an average bioburden in the range 0,1 to 0,9 for multiple or single production batches	24
8 Method 2: Dose setting using fraction positive information from incremental dosing to determine an extrapolation factor	25
8.1 Rationale	25
8.2 Procedure for Method 2A	26
8.3 Procedure for Method 2B	29
9 Method V _{Dmax} -- Substantiation of 25 kGy or 15 kGy as the sterilization dose	33
9.1 Rationale	33
9.2 Procedure for Method V _{Dmax} 25 for multiple production batches	34
9.3 Procedure for Method V _{Dmax} 25 for a single production batch	39
9.4 Procedure for Method V _{Dmax} 15 for multiple production batches	42

9.5	Procedure for Method VDmax 15 for a single production batch	45
10	Sterilization dose audit	48
10.1	Purpose and frequency	48
10.2	Procedure for auditing a sterilization dose established using Method 1, Method 2A, or Method 2B	48
10.3	Procedure for auditing a sterilization dose substantiated using Method VD max 25 or Method VD max 15	51
10.4	Failure of a sterilization dose audit	57
11	Worked examples	57
11.1	Worked examples for Method 1	57
11.2	Worked examples for Method 2	59
11.3	Worked examples for Method Vdmax	67
11.4	Worked example of a sterilization dose audit for a dose established using Method 1, the findings from which necessitated augmentation of the sterilization dose	69
11.5	Worked example of a sterilization dose audit for a dose established using Method 2A, the findings from which necessitated augmentation of the sterilization dose	69
11.6	Worked example of a sterilization dose audit for a sterilization dose substantiated using Method VDmax 25	70
	Bibliography	72
	Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices	74
	Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	75
	Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices	76