

DIN EN ISO 11137-2:2007-09 (E)

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2006, corrected version 2006-08-01)

Contents		Page
Foreword		4
Introduction		5
1	Scope	6
2	Normative references	6
3	Abbreviations, terms and definitions	6
3.1	Abbreviations	6
3.2	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 and verifying the sterilization dose	12
5.1	Nature of product	12
5.2	Sample item portion (SIP)	13
5.3	Manner of sampling	13
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 1,0 for multiple production batches	16
7.3	Procedure for Method 1 for product with an average bioburden 1,0 for a single production batch	21
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	23
8	Method 2: Dose setting using fraction positive information from incremental dosing to determine an extrapolation factor	23
8.1	Rationale	23
8.2	Procedure for Method 2A	24
8.3	Procedure for Method 2B	27
9	Method VDmax -- Substantiation of 25 kGy or 15 kGy as the sterilization dose	30
9.1	Rationale	30
9.2	Procedure for Method VDmax 25 for multiple production batches	31
9.3	Procedure for Method VDmax 25 for a single production batch	34
9.4	Procedure for Method VDmax 15 for multiple production batches	35

9.5	Procedure for Method VDmax 15 for a single production batch	38
10	Auditing sterilization dose	39
10.1	Purpose and frequency	39
10.2	Procedure for auditing a sterilization dose established using Method 1 or Method 2	40
10.3	Procedure for auditing a sterilization dose substantiated using VDmax	42
11	Worked examples	46
11.1	Worked examples for Method 1	46
11.2	Worked examples for Method 2	49
11.3	Worked examples for Method VDmax	58
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	60
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	61
11.6	Worked example of a sterilization dose audit for a sterilization dose substantiated using Method VDmax 25	63
	Bibliography	64
	Requirements of EU Directives 90/385/EEC of 20 June 1990 concerning active implantable medical devices, 93/42/EEC of 14 June 1993 concerning medical devices and 98/79/EC of 7 December 1988 concerning in vitro diagnostic medical devices	66