

DIN EN ISO 11137-2:2023-08 (E)

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:201 3 + Amd 1:2022) (includes Amendment A1:2023)

Contents		Page
	European foreword	4
	European foreword to Amendment	5
	Foreword to Amendment	6
	Introduction	7
1	Scope	8
2	Normative references	8
3	Terms, definitions, and abbreviated terms	8
3.1	Terms and definitions	8
3.2	Abbreviated terms	10
4	Definition and maintenance of product families for dose setting, dose substantiation, and sterilization dose auditing	11
4.1	General	11
4.2	Defining product families	11
4.3	Designation of product to represent a product family for performance of a verification dose experiment or sterilization dose audit	12
4.4	Maintaining product families	13
4.5	Effect of failure of establishment of sterilization dose or of a sterilization dose audit on a product family	14
5	Selection and testing of product for establishing the sterilization dose	14
5.1	Nature of product	14
5.2	Sample item portion (SIP)	15
5.3	Manner of sampling	16
5.4	Microbiological testing	16
5.5	Irradiation	16
6	Methods of dose establishment	16
7	Method 1: dose setting using bioburden information	17
7.1	Rationale	17
7.2	Procedure for Method 1 for product with an average bioburden greater than or equal to 1,0 for multiple production batches	18
7.3	Procedure for Method 1 for product with an average bioburden greater than or equal to 1,0 for a single production batch	24
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	26
8	Method 2: Dose setting using fraction positive information from incremental dosing to determine an extrapolation factor	27
8.1	Rationale	27
8.2	Procedure for Method 2A	28
8.3	Procedure for Method 2B	31
9	Method VD _{max} -- Substantiation of a selected sterilization dose	35
9.1	Selected doses and rationale	35
9.2	Procedure for Method VD _{max25} for multiple production batches	36
9.3	Procedure for Method VD _{max25} for a single production batch	41
9.4	Procedure for Method VD _{max15} for multiple production batches	44
9.5	Procedure for Method VD _{max15} for a single production batch	47

10	Sterilization dose audit	50
10.1	Purpose and frequency	50
10.2	Procedure for auditing a sterilization dose established using Method 1, Method 2A, or Method 2B	50
10.3	Procedure for auditing a sterilization dose substantiated using Method VDmax25 or Method VDmax15	53
10.4	Failure of a sterilization dose audit	59
11	Worked examples	59
11.1	Worked examples for Method 1	59
11.2	Worked examples for Method 2	61
11.3	Worked examples for Method VDmax	69
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	71
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	71
11.6	Worked example of a sterilization dose audit for a sterilization dose substantiated using Method VDmax25	72
Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered		74
Annex ZB (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered		77
Bibliography		79