

# DIN EN ISO 13004:2023-10 (E)

## Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method $VD_{max}^{SD}$ (ISO 13004:2022)

---

Contents	Page
European foreword.....	4
Foreword.....	5
Introduction.....	6
<b>1 Scope.....</b>	<b>7</b>
<b>2 Normative references.....</b>	<b>7</b>
<b>3 Terms and definitions.....</b>	<b>7</b>
<b>4 Definition and maintenance of product families for sterilization dose substantiation and sterilization dose auditing.....</b>	<b>11</b>
4.1 General.....	11
4.2 Defining product families.....	11
4.3 Designation of product to represent a product family.....	12
4.3.1 Product to represent a product family.....	12
4.3.2 Master product.....	13
4.3.3 Equivalent product.....	13
4.3.4 Simulated product.....	13
4.4 Maintaining product families.....	14
4.4.1 Periodic review.....	14
4.4.2 Modification to either product or manufacturing process, or both.....	14
4.4.3 Records.....	14
4.5 Consequence of failure of sterilization dose substantiation or sterilization dose audit.....	14
<b>5 Selection and testing of product for substantiating and auditing a selected sterilization dose.....</b>	<b>14</b>
5.1 Nature of product.....	14
5.2 Sample item portion (SIP).....	15
5.3 Manner of sampling.....	16
5.4 Microbiological testing.....	17
5.5 Irradiation.....	17
<b>6 Method <math>VD_{max}^{SD}</math> — Substantiation of a selected sterilization dose of 17,5 kGy, 20 kGy, 22,5 kGy, 27,5 kGy, 30 kGy, 32,5 kGy or 35 kGy.....</b>	<b>18</b>
6.1 Rationale.....	18
6.2 Procedure for Method $VD_{max}^{SD}$ for multiple production batches.....	18
6.2.1 General.....	18
6.2.2 Stage 1: Obtain samples of product.....	19
6.2.3 Stage 2: Determine average bioburden.....	19
6.2.4 Stage 3: Obtain the selected sterilization dose.....	19
6.2.5 Stage 4: Obtain $VD_{max}^{SD}$ .....	20
6.2.6 Stage 5: Perform verification dose experiment.....	21
6.2.7 Stage 6: Interpretation of results.....	21
6.2.8 Confirmatory verification dose experiment.....	22
6.3 Procedure for Method $VD_{max}^{SD}$ for a single production batch.....	23
6.3.1 Rationale.....	23
6.3.2 General.....	23
6.3.3 Stage 1: Obtain samples of product.....	23

6.3.4	Stage 2: Determine average bioburden .....	24
6.3.5	Stage 3: Obtain the selected sterilization dose .....	24
6.3.6	Stage 4: Obtain $VD_{max}^{SD}$ .....	25
6.3.7	Stage 5: Perform verification dose experiment .....	25
6.3.8	Stage 6: Interpretation of results .....	25
6.3.9	Confirmatory verification dose experiment .....	26
<b>7</b>	<b>Maintaining process effectiveness .....</b>	<b>27</b>
7.1	General .....	27
7.2	Frequency of determination of bioburden .....	27
7.3	Sterilization dose audit .....	27
7.3.1	Frequency .....	27
7.3.2	Outcome .....	28
7.3.3	Procedure for auditing a sterilization dose substantiated using Method $VD_{max}^{SD}$ .....	28
7.3.4	Failure of a sterilization dose audit .....	31
<b>8</b>	<b>Tables of values for SIP .....</b>	<b>32</b>
<b>9</b>	<b>Worked examples .....</b>	<b>57</b>
9.1	Substantiation of a selected sterilization dose of 17,5 kGy (SIP less than 1,0) .....	57
9.2	Substantiation of a selected sterilization dose of 30 kGy (SIP equal to 1,0) .....	58
9.3	Sterilization dose audit for a sterilization dose substantiated using .....	58
9.4	Method $VD_{max}^{22,5}$ .....	58
	<b>Bibliography .....</b>	<b>60</b>