

ISO 10993-7:2008-10 (E)

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

Contents		Page
Foreword		iv
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	2
4.1	General	2
4.2	Categorization of devices	2
4.3	Allowable limits	3
4.4	Determination of EO and ECH residuals	5
5	Product release	10
5.1	General	10
5.2	Release of products without dissipation curve data	10
5.3	Procedure for product release using residue dissipation curves	10
	Annex A (normative) Evaluation of gas chromatograms	12
	Annex B (informative) Gas chromatographic determination for EO and ECH	15
	Annex C (informative) Flowchart and guidance for the application of this part of ISO 10993 series of standards to the determination of EO and ECH residuals in medical devices	19
	Annex D (informative) Factors influencing product residual	26
	Annex E (informative) Extraction conditions for determination of residual EO	28
	Annex F (informative) Rationale for the provisions of this part of ISO 10993	29
	Annex G (informative) Establishment of allowable limits for EO	33
	Annex H (informative) Establishment of allowable limits for ECH	50
	Annex I (informative) Establishment of allowable limits for EG	59
	Annex J (informative) Preparation of EO and ECH standards	63
	Annex K (informative) Ethylene oxide residue measuring methods	67
	Bibliography	74