

ISO 22442-3:2007-12 (E)

Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements	3
4.1	Risk management	3
4.2	Sourcing and manufacturing process	3
4.3	General requirements related to validation	3
5	Literature review	4
5.1	Conduct of the literature review	4
5.2	Application of literature review output	4
5.3	Viruses	4
5.4	TSE agents	4
6	Elimination and/or inactivation study of viruses and TSE agents	5
6.1	General	5
6.2	Protocol	5
6.3	Conduct of the study	6
6.4	Interpretation of data	6
7	Final report	6
8	Review of final report	6
9	Routine monitoring and control of critical process parameters	6
	Annex A (normative) Requirements related to literature review	7
	Annex B (informative) Guidance on the elimination and/or inactivation study for viruses	11
	Annex C (informative) Guidance on the elimination and/or inactivation study for TSE agents	16
	Annex D (informative) Guidance on scaling down	17
	Annex E (informative) Statistical evaluation of virus titres and reduction factors and assessment of their validity	18
	Annex F (informative) Calculation of reduction factors	19
	Annex G (informative) Probability of detection of agents at low concentrations	20
	Bibliography	21