DIN EN ISO 22442-3:2008-03 (E)

Medical devi ces utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 6

4 General requirements 7
4.1 Risk management 7
4.2 Sourcing and manufacturing process 7
4.3 General requirements related to validation 7

5 Literature review 8
5.1 Conduct of the literature review 8
5.2 Application of literature review output 8
5.3 Viruses 8
5.4 TSE agents 8

6 Elimination and/or inactivation study of viruses and TSE agents 9
6.1 General 9
6.2 Protocol 9
6.3 Conduct of the study 10
6.4 Interpretation of data 10

7 Final report 10

8 Review of final report 10

9 Routine monitoring and control of critical process parameters 10

Annex A (normative) Requirements related to literature review 11

Annex B (informative) Guidance on the elimination and/or inactivation study for viruses 15

Annex C (informative) Guidance on the elimination and/or inactivation study for TSE agents 20

Annex D (informative) Guidance on scaling down 21

Annex E (informative) Statistical evaluation of virus titres and reduction factors and assessment of their validity 22

Annex F (informative) Calculation of reduction factors 24

Annex G (informative) Probability of detection of agents at low concentrations 23

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC as amended by Commission Directive 2003/32/EC 25

Bibliography 26