ISO 22442-1:2020 (E)

Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 Risk management process

- 4.1 General
- 4.2 Risk analysis
- 4.2.1 Identification of qualitative and quantitative characteristics related to the safety of medical devices
- 4.2.1.1 Does the device come into contact with the patient or other persons?
- 4.2.1.2 What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the medical device?
- 4.2.1.3 Is the device supplied sterile or intended to be sterilized by the user or are other microbiological controls applicable?
- 4.2.1.4 Are there unwanted outputs of substances?
- 4.2.2 Identification of hazards and hazardous situations
- 4.3 Risk evaluation
- 4.4 Risk control
- 4.4.1 General
- 4.4.2 Risk control for viruses and TSE agents
- 4.4.3 Risk control of other hazards
- 4.4.4 Residual risk evaluation
- 4.4.4.1 General
- 4.4.4.2 TSE risk
- 4.5 Evaluation of overall residual risk acceptability
- 4.5.1 General
- 4.5.2 Documentation
- 4.6 Production and post-production information system

Annex A (informative) Guidance on the application of this document

- A.1 General
- A.2 Application to materials from animal sources
- A.3 Application to materials supplied by third parties

Annex B (informative) Graphical representation of part of the risk management process for medical devices utilizing animal material

Annex C (normative) Special requirements for some animal materials considering the risk management for TSE agents

- C.1 General
- C.2 Collagen
- C.3 Gelatine derived from hides and bones
- C.3.1 General
- C.3.2 Hides as the starting material
- C.3.3 Bones as the starting material
- C.3.4 Manufacturing methods
- C.4 Bovine blood derivatives

C.4.1 General
C.4.2 Traceability
C.4.3 Geographical origin
C.4.4 Stunning methods
C.5 Tallow derivatives
C.6 Animal charcoal
C.7 Milk and milk derivatives
C.8 Wool and its derivatives
C.9 Amino acids
C.10 Peptones

Annex D (informative) Information relevant to the management of TSE risk

D.1 General
D.2 Risks for humans
D.3 Risk management for TSE agents
D.3.1 Principle
D.3.2 Animal species used (see ISO 22442-2)
D.3.3 Geographical sourcing (see ISO 22442-2)
D.3.4 Nature of starting tissue
D.3.5 Slaughtering and processing controls (see ISO 22442-2)
D.3.6 Methods used to inactivate or remove TSE agents (see ISO 22442-3)
D.3.7 Exposure to TSE risk
D.3.7.1 Quantities of animal starting material required to produce one unit of the medical device
D.3.7.2 Quantities of material of animal origin coming into contact with the patients and users
D.3.7.3 Route of administration
D.3.7.4 Estimate of exposure risk

Page count: 29