

ISO 22442-2:2020 (E)

Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General requirements
4.1	General
4.2	Quality system elements
4.3	Procedures
4.4	Personnel
4.5	Current regulatory requirements and guidance
5	Sourcing
5.1	General
5.2	Species and strain
5.3	Geography
5.4	Inspection
5.5	Certification
5.6	Traceability
6	Collection
7	Handling
8	Storage, transport and labelling
Annex A	(normative) Additional requirements relating to the application of this document to bovine-sourced materials and other TSE relevant animal species
A.1	General
A.2	General aspects
A.3	The likelihood of infectivity in the source animals
A.3.1	General
A.3.2	The BSE status of the countries or regions of origin
A.3.2.1	General
A.3.2.2	Negligible BSE risk
A.3.2.3	Controlled BSE risk
A.3.2.4	Undetermined BSE risk
A.3.2.5	Particular circumstances
A.3.3	Sourcing from closed herds starting material
A.3.4	The age of the donor animals
A.3.5	The feeding history of the donor animals
A.4	The infectivity of the source tissue
A.5	Measures to prevent cross-contamination
Annex B	(informative) Certification and attestation ¹ 1 The format in the examples in this annex can be copied.
B.1	Example of a certificate to be issued
B.2	Example of a health attestation to be issued by a veterinarian