

ISO 22442-2:2015-11 (E)

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

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	2
4.1	General	2
4.2	Quality system elements	2
4.3	Procedures	3
4.4	Personnel	3
4.5	Current regulatory requirements and guidance	4
5	Sourcing	4
5.1	General	4
5.2	Species and strain	4
5.3	Geography	4
5.4	Inspection	4
5.5	Certification	5
5.6	Traceability	5
6	Collection	5
7	Handling	6
8	Storage and transport	6
Annex A (normative) Additional requirements relating to the application of this part of Annex B (informative) Certification and attestation		12
Annex C (informative) Veterinary services		14
Bibliography		15