

# ISO 22442-2:2007-12 (E)

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

---

<b>Contents</b>		<b>Page</b>
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
	to bovine-sourced materials .....	7
	Annex B (informative) Certification and attestation .....	13
	Annex C (informative) Veterinary services .....	15
	Bibliography .....	16