

DIN EN ISO 22442-2:2008-03 (E)

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007)

Contents	Page
Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 General requirements	6
4.1 General	6
4.2 Quality System elements	6
4.3 Procedures	7
4.4 Personnel	7
4.5 Current regulatory requirements and guidance	8
5 Sourcing	8
5.1 General	8
5.2 Species and strain	8
5.3 Geography	8
5.4 Inspection	8
5.5 Certification	9
5.6 Traceability	9
6 Collection	9
7 Handling	10
8 Storage and transport	10
Annex A (normative) Additional requirements relating to the application of this part of ISO 22442 to bovine-sourced materials	11
Annex B (informative) Certification and attestation	17
Annex C (informative) Veterinary services	19
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	20
Bibliography	21