DIN EN ISO 22442-2:2016-05 (E)

Medical devices utilizing animal tissues and their derivatives - Part 2: Cont rols on sourcing, collection and handling (ISO 22442-2:2015)

Contents

Page

European foreword ... **3**

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC** ... **5**

Foreword ... **7**

Introduction ... **8**

1 Scope ... **9**

2 Normative references ... **9**

3 Terms and definitions ... **9**

4 General requirements ... **10**
4.1 General ... 10
4.2 Quality system elements ... 10
4.3 Procedures ... 11
4.4 Personnel ... 11
4.5 Current regulatory requirements and guidance ... 12

5 Sourcing ... **12**
5.1 General ... 12
5.2 Species and strain ... 12
5.3 Geography ... 12
5.4 Inspection ... 12
5.5 Certification ... 13
5.6 Traceability ... 13

6 Collection ... **13**

7 Handling ... **14**

8 Storage and transport ... **14**

Annex A (normative) **Additional requirements relating to the application of this part of ISO 22442 to bovine-sourced materials** ... **15**

Annex B (informative) **Certification and attestation** ... **20**

Annex C (informative) **Veterinary services** ... **22**

Bibliography ... **23**