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**Medical devices utilizing animal  
tissues and their derivatives —**

**Part 2:  
Controls on sourcing, collection and  
handling**

*Dispositifs médicaux utilisant des tissus animaux et leurs dérivés —  
Partie 2: Contrôles de l'origine, de la collecte et du traitement*





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# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 General requirements</b> .....	<b>2</b>
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
<b>5 Sourcing</b> .....	<b>4</b>
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
<b>6 Collection</b> .....	<b>5</b>
<b>7 Handling</b> .....	<b>6</b>
<b>8 Storage and transport</b> .....	<b>6</b>
<b>Annex A (normative) Additional requirements relating to the application of this part of ISO 22442 to bovine-sourced materials</b> .....	<b>7</b>
<b>Annex B (informative) Certification and attestation</b> .....	<b>12</b>
<b>Annex C (informative) Veterinary services</b> .....	<b>14</b>
<b>Bibliography</b> .....	<b>15</b>

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 194, *Biological and clinical evaluation of medical devices*, Subcommittee SC 1, *Tissue product safety*.

This second edition cancels and replaces the first edition (ISO 22442-2:2007), of which it constitutes a minor revision.

ISO 22442 consists of the following parts, under the general title *Medical devices utilizing animal tissues and their derivatives*:

- *Part 1: Application of risk management*
- *Part 2: Controls on sourcing, collection and handling*
- *Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*
- *Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes [Technical Report]*