93/42/EEC - Animal Tissue - Conformity Assessment

1. • 93/42/EEC ER#8.2 and EN ISO 22442 applicable
   • 93/42/EEC Rule 17 not applicable

2. • 93/42/EEC ER#8.2 and EN ISO 22442 applicable
   • 93/42/EEC Rule 17 applicable
   • EU Regulation 722/2012 not applicable

3. • 93/42/EEC ER#8.2 and EN ISO 22442 applicable
   • 93/42/EEC Rule 17 applicable
   • EU Regulation 722/2012 applicable
90/385/EEC, 93/42/EEC & 98/79/EC

• 90/385/EEC
  • There are no Essential Requirements that mention animal tissues.
  • EN ISO 22442 – This European Standard has been developed for medical devices regulated by the Medical Device Directive 93/42/EC as amended by 2003/32/EC (see Annex ZA). By analogy, it could be applied for active implantable medical devices regulated by the Active Implantable Medical Device Directive 90/385/EC.

• 98/79/EEC
  • There are no Essential Requirements that mention animal tissues.
  • EN ISO 22442 does not apply to in vitro diagnostic devices.
1. 93/42/EEC ER#8.2 and EN ISO 22442 applicable
   93/42/EEC Rule 17 not applicable
93.42.EEC Annex I

• Essential Requirement #8.2

• Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

• Notified bodies shall retain information on the geographical origin of the animals.

• Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.
EN ISO 22442 – 1, 2 & 3 … + 4

- 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 (PD/ISO TR): Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes
EN ISO 22442 – 1

• Clause 3.1 animal

• any vertebrate or invertebrate [including amphibian, arthropod (e.g. crustacean), bird, coral, fish, reptile, mollusc and mammal] excluding humans (*Homo sapiens*)
93.42. EEC Annex IX

- **Rule 17**
- All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.

- Devices that contact intact skin only
- Tallow or tallow derivatives i.e. stearates
- Milk
- Silk
- Beeswax
- Hair
- Lanolin
93/42/EEC - Animal Tissue - Conformity Assessment

2.

- 93/42/EEC ER#8.2 and EN ISO 22442 applicable
- 93/42/EEC Rule 17 applicable
- EU Regulation 722/2012 not applicable
3. • 93/42/EEC ER#8.2 and EN ISO 22442 applicable
   • 93/42/EEC Rule 17 applicable
   • EU Regulation 722/2012 applicable
2003/32/EC ⇔ EU Regulation 722/2012

- **2003.32.EC:**
  - COMMISSION DIRECTIVE 2003/32/EC – introducing detailed specifications as regards the requirements laid down in 93/42/EEC with respect to MD manufactured utilising tissues of animal origin

- **EU Regulation 722.2012:**
  - COMMISSION REGULATION (EU) No 722/2012 – concerning particular requirements as regards the requirements laid down in 90/385/EEC and 93/42/EEC with respect to AIMD and MD manufactured utilising tissues of animal origin
EU Regulation 722/2012

- Notified Body application for designation – 30 November 2012

- Competent Authority to notify other Competent Authorities and EU Commission of Notified Body designation – 28 February 2013

- The regulation will apply from – 29 August 2013

- Holders of existing MDD Design Examination / Type Examination certificates remain valid – however be aware of changes at time of renewal

- Holders of existing AIMD Design Examination / Type Examination certificates shall apply for a complimentary certificate attesting compliance with the Regulation – these must be issued before 29 August 2014
EU Regulation 722/2012

- Bovine
- Deer
- Elk
- Ovine
- Mink
- Caprine
- Cats

bsi.
EU Regulation 722/2012 – Key Considerations

- QMS
- PMS
- NBMed 2.12
- Vigilance
  - MedDev 2.12-1
- Reactive PMS
- Proactive PMS
- Post Market Clinical Follow-up
  - MedDev 2.7.1 & 2.12-2
EU Regulation 722/2012 - Key Considerations

- Susceptible to transmissible spongiform encephalopathy
- Prevention, control & eradication – EU Regulation 999/2001

- Nature of Starting Tissue
  - Tallow Derivatives – EU Regulation 1069/2009
  - Infectivity – EU Regulation 1069/2009

- Geographical Sourcing
  - European Food Safety Authority (EFSA) – All other species
EU Regulation 1069/2009 – Starting Material

• Collagen, gelatine and tallow used for the manufacturing of medical devices shall meet at least the requirements as fit for human consumption laid down in Regulation (EC) No 1069/2009.

• Rigorous Processing – tallow derivatives – EU Regulation 722/2012 not applicable – from MedDev to Regulation

• Trans-esterification or hydrolysis – 200 °C >20 minutes

• Saponification with NaOH 12 M
  — Batch process
  — Continuous process

• Distillation at 200 °C
EU Regulation 1069/2009 – Starting Material

High Infectivity
- Brain, Spinal Cord, Retina, Optic Nerve, Pituitary Gland

Lower Infectivity
- Peripheral Nerves, Spleen, Lymph Nodes, Esophagus, Stomach, Placenta, Lung, Liver, Kidney, Pancreas, Skeletal Muscle, Tongue, Blood Vessels, Cornea, Cerebral Spinal Fluid, Blood

No Detected Infectivity
- Semen, Placenta, Bone, Heart, Tendon, Gingival Tissue, Skin, Adipose Tissue, Saliva, Sweat, Bile, Urine
EU Regulation 2007/453 – Geographical BSE Risk – Bovine

- **Negligible**
  - Argentina, Austria, Australia, Belgium, Brazil, Chile, Colombia, Denmark, Finland, Iceland, India, Israel, Italy, Japan, Netherlands, New Zealand, Norway, Panama, Paraguay, Peru, Singapore, Slovenia, Sweden, United States of America, Uruguay

- **Controlled**
  - Bulgaria, Canada, Croatia, Costa Rica, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Korea, Latvia, Lichtenstein, Lithuania, Luxembourg, Malta, Mexico, Nicaragua, Poland, Slovakia, Spain, Switzerland, United Kingdom

- **Undetermined**
  - All Others
EFSA – All other species

Confirmed
- Portugal, UK

Likely but not confirmed
- Andorra, Albania, Austria, Belarus, Belgium, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Mexico, South Africa, USA

Unlikely but not excluded
- Botswana, Brazil, Costa Rica, El Salvador, India, Kenya, Mauritius, Namibia, Nicaragua, Norway, Swaziland, Sweden

Highly unlikely
- Argentina, Australia, Iceland, New Zealand, Panama, Paraguay, Singapore, Uruguay
EU Regulation 722/2012

- There is no longer an exemption for medical devices using starting materials for which a TSE certificate of suitability has been issued.
- However the commenting period for these devices will be shortened from 12 weeks to 4 weeks.
93/42/EEC - Animal Tissue - Conformity Assessment

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   • EU Regulation 722/2012 applicable
References

- EU Regulation 722/2012

- EN ISO 22442-1, -2, -3 & -4
  - http://www.bsol.bsigroup.com/

- MedDev 2.11-1 *see next slide

- http://www.oie.int/
MedDev 2.11-1


- Revision 2 – January 2008
- Many aspects moved to EU Regulation 722/2012
  - Need to inform the Notified Body of change
  - Rigorous Processing
  - Summary Evaluation Report

- Revision 3 – draft is consistent with this presentation