

Biological safety – with emphasis on virus inactivation/elimination (EN 12442-3:2000)

BSE has sharpened our view on the aspect of biological safety at all levels. The public, opinion leaders and the authorities agree in their request for more awareness. In 2000 the standard series EN12442 was implemented addressing “Animal tissues and their derivatives utilized in the manufacture of medical devices.” The series consists of three parts and covers the most relevant aspects of risk management, sourcing and handling of material of animal origin. Part three of the series specifies requirements for the validation of the elimination and/or inactivation of viruses and transmissible agents during the manufacture of medical devices.

This bulletin compiles information on the documentation to be provided to demonstrate compliance with part three of the standard.

To whom is this news bulletin applicable?

- Medical device manufacturers utilizing material of animal origin
- Suppliers of medical device components using material of animal origin

Which products are concerned?

The group of affected products includes all medical devices where material of animal origin

- constitute a major part of the product
- is part of the coating/impregnation of the product
- served as an aid to the manufacturing stages of production

Example: If the master cell bank of an organism used for fermentation of a component of a medical device was set up with any material of animal origin this standard is applicable – even if the actual fermentation medium does not include any material of animal origin.

Does this apply to all material of animal origin?

Basically yes, excluded are only

- Milk, hair and wool

However, as the draft of the harmonized ISO 22442 series will cover these materials along with those sourced from non-vertebrate organisms, we strongly recommend the consideration of the standard for all of these materials as well.

www.tuev-sued.com/mhs

What is required from the manufacturers?

- Documents on the systematic approach to gather information on new relevant zoonoses and infectious agents
- A current literature survey on relevant zoonoses
- A validation study on virus inactivation / elimination including
 - The literature survey on relevant zoonoses
 - Information on the production step with potential for inactivation
 - The final test report (signed and dated)
 - The study protocol (including information on the test article, test organism, rationale for the choice of relevant or model organism, indicator cell, virus titer, test method, controls, methods for calculating the results, scaling down, interference and cytotoxicity tests)
 - The raw data
- Such a study is dispensable if the inactivation potential of the processing step under consideration is well established in the scientific literature.

What is assessed by the Notified Body?

TÜV SÜD Product Service GmbH as Notified Body has to establish an evaluation report addressing virus safety. Such report is required before certification or recertification of the medical device utilizing material of animal origin according to Annex II.4. During the audit of manufacturers producing medical devices utilizing material of animal origin one important aspect is the processing step with potential for virus inactivation/elimination. In particular, the relevant in-process controls will be addressed.

Links to informative websites:

<http://www.emea.eu.int/>
<http://www.pheur.org/>
<http://www.pei.de/>
<http://www.ich.org/>
<http://www.rki.de/>

If there are any open questions, please feel free to contact us.

TÜV SÜD Product Service GmbH
Ridlerstr. 65 • D-80339 Munich • Germany
Phone: +49-89-5008-4421 • Fax: +49-89-5008-4403
TÜV Product Service Ltd • Octagon House • Concorde Way
Segensworth North • Fareham • Hampshire • PO15 5RL
Phone: +44 (0) 1489 558100 • Email: info@tuvps.co.uk
This Med-Info can be ordered at: www.tuev-sued.com/mhs