

Medical devices utilizing material of animal origin – the value of transmissible spongiform encephalopathy (TSE) certificates of suitability (EDQM certificates)

TSE certificates of suitability issued by the European Directorate for the Quality of Medicines (EDQM) confirm the compliance of a substance with the relevant monograph of the European Pharmacopoeia PA/PH/SG (01) 24 DEF – 5.2.8: Minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products.

As the clinical benefit is not evaluated by the EDQM experts, these certificates do not confirm the TSE safety of the product. The risk associated with the transmission of TSE depends not only on the source material but also on the intended use of the product and the route of administration.

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

Does this apply to all material of animal origin?

Applicable to TSE-relevant species such as:

- Cattle, sheep, goats, deer, elk, cat, mink

The consultation process according to Directive 2003/32/EC:

Directive 2003/32/EC, article 5, 3rd paragraph details:

“Notified bodies shall, during the evaluation of the risk analysis and risk management in the framework of the conformity assessment

procedure, take account of the TSE certificate of suitability issued by the European Directorate for the Quality of Medicines, hereinafter TSE certificates, where available.”

The 4th section of this article specifies that for raw materials or medical devices that have been issued a TSE certificate, a consultation with all European competent authorities is not required. However, the national competent authorities may request an evaluation of these products that is to be documented in a report. The report is to be made available to the competent authorities upon request.

The German Competent Authority requires that the report is to be provided for review prior to certification of the device.

Validity of EDQM certificates:

TSE certificates of suitability are issued for a period of five years. They will not be renewed automatically. The manufacturer has to apply for the renewal.

Furthermore, the validity of a current TSE certificate cannot be deduced from the certificate itself, as these certificates remain valid only if

- The substance continues to be manufactured in accordance with a suitable quality assurance system (e.g. GMP, ISO 9000, HACCP)
- No changes are introduced with regard to
 - the manufacturing method,
 - the country of origin of the raw material, or
 - the nature of the source tissue

The manufacturer of a medical device that utilizes EDQM-certified material of animal origin is held responsible to gather current information concerning these aspects.

What is required from the manufacturers?

- Contractual agreements with the suppliers of raw material detailing the requirements for information if any relevant changes are introduced
- Documents on the systematic approach to gather information on the TSE status of the country of origin of the raw material
- Documents on the systematic approach to gather information on the risk category of the source tissue
- A current literature survey on relevant zoonoses including infectious agents like TSE

What is assessed by the Notified Body?

TÜV SÜD Product Service as a Notified Body has to establish an evaluation report addressing TSE safety. Such a 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, important aspects are the processing step with potential for TSE inactivation/elimination or cross-contamination. In particular, the relevant in-process controls will be addressed.

When applicable, contractual agreements with the supplier of raw material will be checked with regard to the requirement of information on any relevant changes that are introduced (manufacture, source country, type of raw material). In addition, the systematic approach to gather relevant current information will be checked.

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.

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