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New EU Regulation No. 722/2012

Impact on holders of CEPs
for the TSE risk

07 February 2014
in Strasbourg

AC29-Reg722-f16-100x210-w-13-10-21

TÜV SÜD Akademie GmbH
TÜV SÜD Product Service GmbH

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New EU Regulation No. 722/2012 – Impact on holders of CEPs for the TSE risk

The new EU Regulation No. 722/2012 for active implantable medical devices and medical devices manufactured utilising tissues of animal origin introduces new requirements for the medical device industry, authorities, manufacturers and Notified Bodies.

We familiarise you with the content of the regulation and the changes it introduces to ensure a high level of safety and health protection. We inform you about the changes in conformity assessment, documentation, risk evaluation and management, EC design etc. and the different perspectives, interpretations and discussions by various parties.

Contents

Dr. Vikas Jaitely, MHRA: Information on novel requirements for consultation according to EU Regulation No. 722/2012

- Clarification of the regulatory procedure
- How shall the report of the Notified Bodies be circulated?
- Deadline for comments/handling of comments etc.
- How to avoid pitfalls during the submission?

Hélène Bruguera, EDQM: Introduction to the EDQM certification procedure for materials with a TSE risk

- Description of the procedure
- Outline of the EDQM certification policy for materials presenting a TSE risk
- Who is permitted to access assessment reports from EDQM?
- Changes/revisions/renewals of CEPs

Prof. Blümel, PEI: Update on CEP for TSE/BSE-relevant material

- Content of evaluation report from EDQM: Some parties regard the EDQM TSE-CEPs as a documentation of “tissue and origin” while others regard them more as an assessment of safety/suitability

Prof. Sabine Kloth, TÜV SÜD Product Service GmbH:
Introduction to the content of the evaluation according to EU Regulation No. 722/2012

- Content of evaluation report (SER) from Notified Bodies
- Consultation procedure
- Audit requirements
- Significant changes
- Renewal

Dr. Susana Wäsch, Geistlich Pharma AG:

The manufacturer’s perspective

- Application and reporting
- Acceptance of EDQM-TSE CEPs for medical devices outside the EU?

Round table discussion

Moderation: Dr. Bassil Akra, TÜV SÜD Product Service GmbH (MHRA, EDQM, TÜV SÜD, Geistlich Pharma AG)

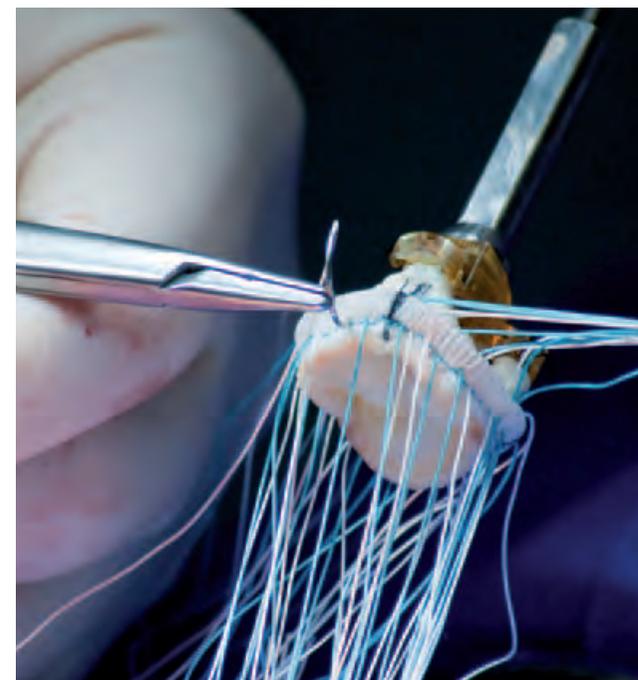
- Requirements for reporting of significant changes – a comparison
- Requirements for the separation of production lines
- Important topics to be covered during audits of procurement and production sites

Participants

- CEP holders for the TSE risk
- Medical device manufacturers
- Medical device authorities
- Managers Regulatory Affairs
- Managers Development
- Quality Managers

Note

The training course will be held in English.



Certificate:	Certificate of attendance TÜV SÜD Akademie
Date:	7 February 2014 in the EDQM premises, Strasbourg, France
Duration:	1 day
Fee:	720,00 € attendance fee (plus VAT) 856,80 € final price incl. 19 % VAT
Product link:	www.tuev-sued.de/akademie/4611078

Your benefits:

- Gain quick and concise insights into the complex requirements of the new EU Regulation No. 722/2012.
- Obtain an overview of the efficient and safe processes for the registration of active implantable medical devices and medical devices manufactured utilising tissues of animal origin.
- Avoid pitfalls during the preparation of regulatory documentation in accordance with the new EU Regulation No. 722/2012.



Registration

please fax to: **+49(0) 800 2523329**

(Please fill out in CAPITALS)

Or register online:
www.tuev-sued.de /akademie



Akademie

**Choose certainty.
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Event

Title _____
Date _____ Place _____

Participant

Mr. Ms. Title _____
Surname _____ First name _____
Telephone (business) _____ Fax (business) _____ Department _____
Function _____ E-Mail (business) _____

Address

Private Company (please tick) Company _____
Street _____ ZIP/ Town/ Country _____
Industry _____ Number of employees _____

Billing address (if different) Your internal order no. (if available) _____

Contractual correspondence desired:

by post by email by fax
 to participant Additionally to: _____

Consents

We, the TÜV SÜD Academy, have committed ourselves to avoiding environmental pollution as far as possible and to conserving resources. Please support us in these matters. Indicate your agreement so that we can send you information on our courses by email in future.

Yes, please inform me by email about your products and services for training courses and certifications as well as your technical conferences.

Email address (if different from that above): _____

With my signature I confirm that the TÜV SÜD Academy and the companies of the TÜV SÜD Group (consultancy, testing and certification of companies and products) may use my data for customer analyses and written advertising (e. g. information on seminars offered) by post. **(Please cross out if not applicable).**

Signature

Date/Place _____ Signature _____

Notes on data protection: The TÜV SÜD Akademie GmbH, Westendstr.160, 80339 München and its service providers use your personal data for processing the service booked. We also inform our business customers by telephone about our products and services for continuing education and training and certification, as well as our technical conferences.

If you do not agree with the use of your personal data for advertising or market research purposes or wish to withdraw a corresponding consent, just send a short message by post to TÜV SÜD Akademie GmbH, AKD Datenschutz, Westendstr. 160, 80339 München or by email to akd.datenschutz@tuev-sued.de.

GENERAL TERMS & CONDITIONS

TÜV SÜD Akademie GmbH

Hereinafter, parties who contract with TÜV SÜD AKADEMIE GmbH are referred to as **Participants**, and TÜV SÜD AKADEMIE GmbH is referred to as the **Academy**. Together, Participants and the Academy are referred to as the **Contracting Parties**.

1. Scope

Offers made by and services provided by the Academy shall always be subject to these General Terms & Conditions. Amendments shall only be valid if agreed in writing.

2. Services Offered; Drawing up of Agreements; Cancellation

2.1 Offers made by the Academy are provisional and non-binding. This also applies to the prices offered. Orders relate to agreed activities or other services and not to an outcome.

2.2 The Participant may register with an Academy Training Center or issue an order in writing, via fax or online. Registration or an order issued is binding as soon as the Participant receives a written order confirmation.

2.3 Registration or orders may be cancelled in writing; provided the withdrawal notice is received at the latest 14 working days before the start of the event, nothing is payable; 50% of the price is payable if the withdrawal notice is received no later than 3 working days before the start of the event; the full price is payable if the withdrawal notice is received any later than that, or if the Participant fails to appear or leaves the event prematurely. In the case of an event lasting longer than 3 months, provided the withdrawal notice is received no later than 7 working days before the start of the event, a pro rata price in an amount equivalent to 3 months is payable (subject to other provisions from entities providing support). The postmark date shall be used as the basis for determining whether these deadlines have been met. Arranging a replacement Participant is permitted. The statutory right to cancel shall remain unaffected.

2.4 The Academy may subcontract part of an order to a third party without the Participant's approval, provided the third party meets the requirements of the Academy's quality management system.

3. Payment Terms

3.1 Unless individual contractual provisions state otherwise, applicable prices are as published in current event programs. Prices are payable in full immediately to one of the indicated accounts upon receiving an invoice, and the invoice number must be shown. The Academy reserves the right to demand cash payment or advance payment as a prerequisite for participating in the event in question.

3.2 All prices are payable plus statutory value-added tax as specified by law (exceptions pursuant to § 4 Nr. 21 of Germany's Value-Added Tax Act [UStG] shall be indicated as such). The final prices shown in the programs include the value-added tax applicable on the day of printing. If the value-added tax rate is increased by law after the event program comes out, the Academy is entitled to charge accordingly.

3.4 An event may not be spread across more than one Participant. A partial booking with reduced price is not permitted, unless explicitly stated in the program.

4. Implementation of Events

4.1 Events shall be carried out in accordance with the published event program and based on any separate agreement with the Participant. However, the Academy reserves the right to make changes insofar as this does not fundamentally alter the event's objectives.

4.2 Demanding that an event be carried out by a specific instructor or at a specified place of instruction is not permitted. Demanding compensation for a missed day of an event is not permitted.

4.3 The Academy reserves the right to postpone or cancel an event for reasons for which it is not itself to blame, e.g. instructor is sick, insufficient number of participants. It shall notify the Participant of such cancellation by sending a notification to the address provided during registration. If an event is cancelled, participation fees already paid shall be refunded. Subject to the provisions in Section 6, the Academy shall not bear responsibility for wasted expenditure or other disadvantages affecting the Participant as a result of the cancellation.

5. Intellectual Property Rights and Copyright

5.1 Documents, software and other media given to the Participant during the event are protected by copyright. It is not permitted to duplicate, forward or otherwise make use of such materials (including excerpts) without explicit written permission from the Academy.

5.2 CD-ROM products and accompanying documentation purchased by the Participant are intended for own use by the Participant, who shall be assigned simple, non-transferable utilization rights. By entering into the purchase agreement, the Participant shall be deemed to have accepted the applicable license conditions.

5.3 Any use of the TÜV SÜD logo apart from on the certificate or certification issued (e.g. on business cards) requires explicit written permission from the Academy.

6. Liability

6.1 The Academy shall be liable for damages, regardless of the legal grounds, only if it caused the damages intentionally or as a result of gross negligence or if it negligently infringed a major contractual obligation ("cardinal obligation"). If it infringes a

major contractual obligation, the Academy shall in all instances only be liable for foreseeable damages typical to the agreement at the time the agreement was drawn up.

6.2 Insofar as the Academy is liable for damages arising from negligence due to having infringed major contractual obligations per Section 6.1 above, the amount for which it is liable per case of damage shall be limited as follows: €500,000 for property damage and €125,000 for pecuniary damage.

6.3 There shall be no liability for damages resulting from the infringement of minor contractual obligations due to ordinary negligence.

6.4 "Major contractual obligations" are defined as obligations that protect any of the Participant's legal positions which relate to the agreement and which the agreement is to uphold based on its content and objectives; furthermore, a contractual obligation shall be deemed major if it is a prerequisite for proper fulfillment of the agreement and the Participant ordinarily expects and may reasonably expect it to be fulfilled.

6.5 The exclusion and limitation of liability described in Sections 6.1–6.3 does not apply to damages to life, body or health, nor does it apply to claims based on a quality guarantee or pursuant to Germany's Product Liability Act [ProdHaftG].

6.6 Insofar as damages claims against the Academy are excluded or limited, this also applies to the personal liability of the Academy's decision-making bodies, experts, other employees or their agents.

6.7 Aside from consumer goods purchases or consumer agreements subject to § 651 of the German Civil Code, damages claims not subject to the limitation provisions in § 438 Section 1 No. 2 or § 634a Section 1 No. 2 of the German Civil Code shall be statutebarred after one year following the transfer of risk.

7. Place of Jurisdiction; Place of Fulfillment; Applicable Law

7.1 For both contracting parties, the place of jurisdiction for asserting claims is the Academy's headquarters, insofar as the prerequisites pursuant to § 38 of Germany's Code of Civil Procedure are met.

7.2 The place of fulfillment for all obligations arising from the agreement is the Academy's headquarters.

7.3 The contractual relationship and all resulting legal relationships are subject to German law (German national law to the exclusion of the conflict-of-law provisions and to the exclusion of UN CISG).

8. Applicability; Other

8.1 These General Terms & Conditions apply to companies and all legal persons under public law and special funds under public law as defined in § 310 of the German Civil Code, unless explicitly indicated otherwise.

8.2 If the Participant is not included among the persons pursuant to § 310 of the German Civil Code per Section 8.1 above, these General Terms & Conditions shall apply subject to the following proviso:

Section 7.1 shall apply, subject to the proviso that the Academy's headquarters shall be deemed the place of jurisdiction if the Participant moves its headquarters, domicile or usual residence outside the scope of German law, or if its headquarters, domicile or usual residence is unknown when the action is brought. – Section 7.2 does not apply.

Cancellation Rights Notice

Right to cancel: A Participant who as a consumer has registered or issued an order exclusively via remote telecommunications may cancel within 14 days in text form (e.g. letter, fax or e-mail) without providing grounds. This cancellation period begins when the Cancellation Rights Notice is received in text form, but not before order confirmation (i.e. drawing up of an agreement) and not before the obligation to provide information pursuant to Article 246 § 2 in combination with § 1 Sections 1 and 2 of the Introductory Act to the German Civil Code [EGBGB] has been fulfilled. To meet the cancellation period deadline, sending the cancellation in a timely manner shall suffice. The cancellation must be sent to: TÜV SÜD Akademie GmbH, Westendstrasse 160, 80339 Munich, Fax 089-5791-2671, E-mail: akademie@tuev-sued.de

Consequences of cancellation: In the event of an effective cancellation, the goods/services/payments received by either side must be returned, and if appropriate any benefits (e.g. interest) must be surrendered. If the Participant cannot return the goods/services in full or in part, or can only return them in an impaired state, the Participant must provide monetary compensation. This may mean the Participant has to meet the contractual payment obligations for the period leading up to the cancellation. Obligations to render payments must be met within 30 days. For the Participant, this deadline begins when the cancellation is sent; for the Academy, the deadline begins when the cancellation is received.

Please note: The right to cancel expires if the agreement has been fully fulfilled by both sides per the Participant's explicit request before the Participant has exercised the right to cancel.

[End of instructions regarding cancellation]