

Réponse de l'organisme de certification allemand TÜV Sud

- **When did you deliver the CE label to Conceptus implant, Essure? For how long? Was it renewed?**

We have given grant for use of CE0123 label for Conceptus Inc. on 05.12.2001. The grant had been returned by the client on 07.06.2004 before end of validity.

- **Could you explain a little how does the CE label system work? What do you control exactly?**

The grant for marking was given under the formerly EU Medical Devices Directive MDD 93/42 EEC (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042>)

- **Did the documents presented by Conceptus guarantee the safety of the implant for women?**

Please be aware that we have – under the rules of accreditation – private contracts with the applicants and the content of the files are not subject to public. But as we have given grant for marking with our CE0123 marking, the answer to your question is obvious.

- **How much did Conceptus pay you for your organization's work?**

Please be aware that we have – under the rules of accreditation – private contracts with the applicants and the content of the files are not subject to public. According to the rules of accreditation we are working under ISO 60065, this means that the fees born for certification must be payed by the applicant.

- **In 2017, the NSAI suspended Essure's label for three months and was never renewed. Any comments on that?**

No, we are working in this field as a Notified Body of the European Commission. Any activities 13 years after our grant are not monitored by us, because under common understanding this may not be anymore the product we had under investigation.